Medvacon Life Sciences

Capabilities

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Example Project Overviews

Medvacon Life Sciences delivers leading Quality Compliance and Technical Services that are designed to help reduce the overall cost of compliance for Life Sciences organizations. We offer our clients comprehensive services, including leadership and a range of strategic solutions and tactical services that provide cost-effective and comprehensive compliance and validation as well as Talent Acquisition solutions. The Medvacon Life Sciences team of highly-qualified consultants can deliver a broad suite of solutions in all areas within Pharmaceuticals, Biotechnology, Cell Therapy, Medical Devices as well as CDMOs, Warehousing, Pharmacies and other support services.

Medvacon Life Sciences Capabilities

Overview Contents:

From concept development through design, installation, start-up, commissioning, qualification and validation, Medvacon offers single-source responsibility and acts as a point of contact to drive and deliver your project-specific needs. Medvacon Life Sciences believes in a simple principle: SCOPE, COST,

SCHEDULE. Three simple words that when planned and implemented appropriately lead to project success every time. With a staff of professionals maintaining diverse educational backgrounds and considerable experience, Medvacon Life Sciences gets the job done right the first time. From full-service Commissioning / Qualification to Validation and Compliance consulting services to Engineering and Architecture, Medvacon Life Sciences delivers on time, on budget and with the highest level of quality. Below is a partial list of services.

Partial List Of Services Contents:

If you would like to have an initial, no obligations, consultation with an expert to discuss your project, please feel free to contact us at 833-MEDVACO.

MEDVACON SARS-COV-2 (COVID-19) INVOLVEMENT:

With the onset of the recent SARS-CoV-2 (COVID-19) outbreak biopharmaceutical companies have stepped up activities to bring vaccines to market. Medvacon Life Sciences has supported biopharmaceutical clients to ensure that their facilities, utilities, equipment, cleaning and processes are validated to support the expedited time to market.

> *"We are proud to be supporting companies developing mRNA-based products in support of the ongoing efforts to develop a COVID-19 vaccine," said Joe Toscano, one of the founding members of the life sciences company. "We have a depth of industry experience and expertise to support these companies in rapidly developing markets and launching their new products to meet the urgent demands of COVID-19 vaccine development," he continued.*

As current demand for commercial-scale GMP (Good Manufacturing Practices) RNA and plasmid products have seen rapid growth recently, and pharmaceutical, vaccine, and biotech companies are rapidly expanding their current manufacturing capacity to meet demand. RNA stands for ribonucleic acid, a nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins, although in some viruses, RNA rather than DNA carries the genetic information. DNA is a self-replicating material that is present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information.

Medvacon is helping to expand current manufacturing capacity to best-in-class GMP capping reagents with GMP filling capabilities at full commercial scale, including the design and building of state-of-the-art facilities for mRNA and DNA-based components in support of commercial-scale GMP production. Medvacon is supporting clients in the areas of validation support activities, including: equipment qualification, facility and utility qualification, cleaning validation, validation planning, supporting quality documentation, as well as conducting process verification & validation The FDA defines process validation as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

In addition to ensuring the technical aspects of development and commercialization are complianct with regulatory agencies, Medvacon can assist biopharmacetical companies with bringing their vaccine to market. Please see the Section titles: "PRODUCT LAUNCH MARKETING PLAN DEVELOPMENT" near the end of this capabilities document on page 25 for more information on how Medvacon can assist with product launch and marketing.

Medvacon Life Sciences delivers leading Compliance and Computer System Validation services that are designed to help reduce the overall cost of compliance for Life Sciences organizations. We offer our clients comprehensive services, including leadership and a range of strategic solutions and tactical services that provide cost-effective and comprehensive compliance and validation. The Medvacon Life Sciences team of highly-qualified consultants can deliver a broad suite of solutions in areas of computer systems validation, infrastructure qualification, IT Quality Management, and process improvement.

- Risk-Based Computer System Validation
- Software QA and User Acceptance Testing
- Software Vendor Audits
- Gap Assessments and Remediation
- SDLC Methodology Development
- SOP Development
- Project Management
- 21 CFR Part 11 Compliance and Assessments
- IT Policies and Procedure Development

Computer Software Validation is a formalized, documented process for testing computer software and systems, required by 21 CFR 11.10(a) and Annex 11, Section 4. The FDA and other regulatory bodies require validation to demonstrate that computer systems are in compliance with all regulations for electronic data management systems. Failure to validate systems is one of the leading reasons a business is issued a 483. Medvacon Life Sciences can validate all of your software, databases, spreadsheets, and computer systems, and develop the appropriate documentation for all phases of the software life cycle. We have written and executed validation packages for systems of all sizes. We can provide any level of service required, from executing test scripts generated from your existing specifications to writing the entire validation package. Medvacon Life Sciences will follow your existing validation procedures or provide your company with validation standards. Our validation methodology ensures validation deliverables that are in line with industry standards & best practices, focus resources towards the most critical system functions, and complete the validation projects efficiently.

Example Projects

Lab Systems Software Implementation & Validation

Medvacon Life Sciences' Pharmaceutical client planned on deploying Waters Empower 3 Chromatography software in their facilities for use with approximately 30-35 HPLCs. To ensure compliance with current Good Manufacturing Procedures, Pharmaceutical Company engaged Medvacon Life Sciences to perform Computer System Validation activities for the implementation. Medvacon Life Sciences' activities included the following scope of work: Prepare the User and Functional Requirements (URS/FRS) and the Traceability Matrix (TM); Review Waters vendor software testing documentation per Detailed Design Specifications (DDS) including software modules, graphics, HMI components and batch reports; Review Configuration Specification/DDS documents against requirements; Author IOQ leveraging the vendor IOQs for the Waters Empower 3 Chromatography Data Software; Execute IOQ and prepare the IOQ summary

report; Author PQ for the live environment; Execute PQ for the live environment; Prepare PQ for summary report; Author data transfer and integrity testing protocol for transfer of data from Empower 2 to Empower 3; Execute data transfer and integrity testing protocol, Prepare Summary Report; Prepare Validation Summary Report and final Traceability Matrix; Support deviation closure; Support developing SOP's; Generation of VSR; documentation; Provide Project Oversight and Management (PM)

21 CFR Part 11 & CSV Methodology Assessment

Medvacon Life Sciences was engaged in a multifaceted compliance consulting initiative. Medvacon Life Sciences provided professional consulting services in the area of 21 CFR Part 11 compliance as well as requisite requirements such as System Development Life Cycle (SDLC) and Validation. Medvacon Life Sciences specifically provided: written 21 CFR Part 11 compliance assessment reports for the five types of computer controlled test equipment at client; written assessment report of the client site IT Policies & Procedures to ensure 21 CFR Part 11 compliance controls; written assessment report of site IT Policies & Procedures governing their System Development Life Cycle (SDLC) methodology required for developing software used in a GxP environment; Validation and 21 CFR Part 11 compliance consulting services specific to client's in-house developed MS Access based test-data collection and reporting system.

21 CFR Part 11 & CSV Methodology Assessment

Medvacon Life Sciences was engaged by our partner to assist FDA lab staff by identifying where in their SOPs updates for LIMS needed to be made far in advance of the lab implementation. Medvacon Life Sciences ensured that the LIMSrelevant SOPs from the labs and QMS staff were available. This included instrument qualification, operational qualification, and performance qualification (IQ/OQ/PQ).

QMS Software Quality Assurance & Validation

An industry leader in Quality Management Software has engaged Medvacon Life Sciences in a multitude of ongoing CSV, SQA and PM activities. Medvacon Life Sciences has a dedicated team that prepares and executes PQ's for QMS providers' client implementations. Medvacon Life Sciences has another dedicated team that conducts full SQA and validation of QMS providers' quarterly software releases.

PDMA Sample System Validation

Medvacon Life Sciences' client that provides Prescription Drug Marketing Act (PDMA) sample compliance services engaged Medvacon Life Sciences to validate their acknowledgement of delivery tracking system. Medvacon Life Sciences developed the project plan, Validation Plan, reviewed the URS and FRS, developed the IQ/OQ and PQ. Medvacon Life Sciences executed the protocols and developed the validation final report.

Pharmaceutical IT Policies & Procedures Development

A Pharmaceutical company focused on developing small-molecule anti-cancer therapeutics engaged Medvacon Life Sciences to evaluate their existing IT Policies and Procedures and develop an overarching IT Quality System, along with development of requisite documents. Medvacon Life Sciences developed sixty-four IT Polices, Procedures and Work Instructions which form the basis of their IT Quality System.

EQUIPMENT, FACILITIES & UTILITIES QUALIFICATION (CQV)

Equipment Qualification comprises a series of qualifications, such as Design, Installation, Operational, and Performance Qualification, that provide a high degree of assurance of the consistent, expected functioning of a piece of equipment. Operating parameters and environment, as well as documented routine maintenance and on-going performance checks, contribute to a life-cycle approach to maintaining equipment in a validated state. Medvacon Life Sciences' experienced team of equipment qualification experts can assist you with equipment needs including:

- Manufacturing and Process Equipment
- Laboratory Equipment and Instrumentation
- Packaging Equipment
- Warehouse Equipment and Systems
- Medical Device Assembly Lines
- Medical Device EQ

Medvacon Life Sciences' Facilities and Utilities Commissioning and Qualification specialists help clients ensure their facility, utilities, and equipment perform as intended. We do that through commissioning and qualification services, using a risk-based approach to maximize time and cost efficiencies through focused qualification efforts. Our experienced commissioning and qualification team has the technical skills and experience to make our clients' projects successful. By using current industry trends and methods to help define and implement best practices, we quickly adapt to the needs of each individual client, knowing each project has unique requirements.

Example Projects

Packaging Equipment / Line Qualification

A Pharmaceutical client engaged Medvacon Life Sciences to design and implement a matrix approach to qualifying all of their OSD packaging lines to ensure fully compliant validation in the most cost effective and efficient manner. Medvacon Life Sciences' team of experts evaluated all of the client's product specifications and all of the packaging line specifications and capabilities to develop and implement the matrix approach. Medvacon Life Sciences further evaluated the existing equipment qualification protocols to identify gaps. For the gaps, Medvacon Life Sciences qualified each piece of packaging equipment to the new intended uses and conducted performance qualifications of the

integrated packaging lines. This approach allows the client to onboard new products to the packaging lines with a systematic, compliant, efficient and defendable validation approach.

Manufacturing Equipment Qualification

A Pharmaceutical client that manufactures oral solid dose (OSD) tablets engaged Medvacon Life Sciences to qualify their production equipment. Medvacon Life Sciences developed and executed Installation and Operational Qualification (IQ/OQ) protocols for Mixers, Blenders, Fluid Bed Driers and Tablet Presses.

HVAC, Air Compressors & Dust Collection Qualification

A Pharmaceutical client engaged Medvacon Life Sciences on a multitude of Facility Qualification Activities. The engagement included the qualification of: 16 Air Handling HVAC Units, 2 Facility-Duty Air Compressors and 2 Dust Collection units all servicing the GMP Packaging and Lab areas. Medvacon Life Sciences' Team of Utility Qualification Engineers developed and executed Installation and Operational Qualification (IQ/OQ) protocols for all of the equipment and developed all of the qualification reports.

Medical Device Component Manufacturing

Medvacon Life Sciences was engaged by a Medical Device Component manufacturer to evaluate the impact on equipment qualification related to the planned relocation of the manufacturing facility. Medvacon Life Sciences identified components from the point of order generation to the completion of manufacturing to the movement of the component to shipping. The manufacturing process was assessed for reproducibility and operational efficiency and a report was developed for the manufacturer to satisfy their medical device customer's quality units.

Flammable Mixing Vessel Containment

A Pharmaceutical company that manufactures various types of products engaged Medvacon Life Sciences to evaluate the design for their Flammable Mixing Vessel, Explosion Proof Room and transmission of the product to the filling line for packaging. Medvacon Life Sciences conducted a regulatory and design analysis of the process, room, equipment and transmission lines that the client used for regulatory compliance.

Covid-19 Support

A biotech firm preparing for launch of a new product in support of a Covid-19 vaccine engaged Medvacon to provide expert guidance to the approach and execution of facilities and equipment qualification in support of the new product launch. Medvacon's scope included generating a validation master plan, authoring the facilities validation documents associated with the facilitates and equipment, providing support for cleaning validation, conducting an initial cleaned gap assessment followed by authoring the cleaning validation master plan, providing guidance for the development of the cleaning program, and providing the Process Validation protocol development, review, execution, and report writing.

PROCESS & CLEANING VALIDATION (PV/CV)

Process Validation applies to the production of pharmaceuticals and intermediate products as well as the manufacture of medical devices. Per the FDA Process Validation Guidance, "process validation is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product." This entails

on-going documentation and assessment of all constituent elements of the process, such as materials, equipment, operations, and environmental conditions. The primary goal is to gain understanding and control of process variation and its effect on process outcome. Medvacon Life Sciences' team of process validation experts can assist with design of process validation methodologies as well as development and execution of process validation protocols in both pharmaceutical and medical device

Cleaning Validation is just as important as process validation when it comes to the safety and continued compliance of any manufacturing firm. Medvacon Life Sciences has the experience and knowledge to help our clients develop and verify that their manufacturing equipment consistently removes process soils before the next manufacturing run to ensure clean, uncontaminated equipment. Our highly trained staff is experienced in developing and executing cleaning development and cleaning validation master plans and protocols in line with current industry standards. We provide a hands-on approach to help guide our clients through the details of establishing a cleaning master plan, setting residue acceptance criteria, preparing a comprehensive sampling plan, and validating and utilizing appropriate qualified analytical methods with sufficient sensitivity for those unique processes and equipment.

Example Projects

Pharmaceutical Cleaning & Process Validation

A Pharmaceutical client engaged a senior Medvacon Life Sciences expert to oversee the Process & Cleaning Validation Group and manage all process and cleaning validation activities for the site. Additional Medvacon Life Sciences experts were brought in to handle all aspects of several process and cleaning projects. The Medvacon Life Sciences team developed the process and cleaning validation protocols and coordinated with manufacturing and quality personnel to pull and analyze process validation samples and cleaning swabs.

Contract Manufacturer Process Troubleshooting

A Pharmaceutical client engaged Medvacon Life Sciences to travel to their contact manufacturing site to troubleshoot a pharmaceutical process that was producing unwanted particulates in an aseptic process. Medvacon Life Sciences identified the issue in the process and developed a technical report with a solution. The fix was implemented and production was able to resume averting costly rejected batches and production delays.

Biopharmaceutical Process Validation

A biopharmaceutical company specializing in applying deuterium chemistry to known molecules to create novel therapies with the potential for improved safety and efficacy profiles engaged Medvacon Life Sciences to oversee the process validation activities at their contract manufacturer. In addition to many other activities, Medvacon Life Sciences reviewed the process validation protocols and oversaw the entire validation process to ensure compliance. The product received FDA approval and Medvacon Life Sciences remains engaged overseeing CMC and Clinical Supply activities.

Medical Device Cleaning Validation

Medvacon Life Sciences was engaged by our medical device client to provide technical and regulatory assistance in assessing the impact that a small facility fire had to one manufacturing area used for the production of medical devices for multiple clients. Medvacon Life Sciences provided initial remediation plan guidance and assisted the Client in developing customer specific remediation plans including cleaning and component disposition. Medvacon Life Sciences

also participated on client conference calls providing medical device compliance expertise. Medvacon Life Sciences was additionally engaged to develop a overall Cleaning Validation Plan for the company.

ASEPTIC OPERATIONS EVALUATION & REMEDIATION

Medvacon will perform a targeted assessment or an overall end-to-end assessment of the aseptic manufacturing operations identified in the bullets below. For end-to-end assessments, Medvacon Senior Consultants will observe manufacturing operations on all shifts over a multi-week period. During this initial observation period, the consultants will observe and learn how the technicians perform and execute the processing steps. During the observation and learning period, the consultants will provide monitoring and mentoring of the technicians. After the multi-week period, the Medvacon consultants will provide an overall assessment of the operation to senior management along with recommendations for improvement. These recommendations will cover The FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice:

- Buildings and Facilities
- Environmentatl Monitoring Personnel Training, Qualificaiton & Monitoring
- Endotoxin Control
- Time Limitations
- Validation of Aseptic Processing and Steriliztion
- Media Fills
- Laboratory Controls
- Sterility testing

Following discussions with senior management, Medvacon will provide new or enhanced training or refresher training for the technicians if needed. Some of this training may be in conjunction with reularly scheduled staff training to reinforce Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP). Once training is complete, the Medvacon consultants will reassess the operators' manufacturing execution progress. Additional shift observations will be conducted post-training as part of the reevaluation. Further recommendations to senior management will be provided. Medvacon will provide a report of post-training observations and assessment of the mentoring and training effectiveness.

Example Projects

End-to-End Assessment - Nucleotides, Nucleoside Triphosphates, and Oligos Manufacturer

Medvacon Life Sciences was engaged by an Aseptic Nucleotides, Nucleoside Triphosphates, and Oligos Manufacturer to conduct an end-to-end assessment of the facility. In addition, Medvacon was engaged to provide on the job coaching and classroom training of the technicians to ensure proper aseptic operation.

Aseptic Manufacturing Site Gap Assessment - Pharmaceuticals

Medvacon Life Sciences was engaged by a pharmaceutical client to conduct a gap analysis of their manufactuing operational facilities and quality systems for the manufacturing of their aseptic product against the current requirements and expectations as well as draft Annex 1 guidance for manufacture Aseptic Drug Products distributed in the EU and UK. In addition, gap analysis of the entire manufacturing process from receipt of raw materials through batch testing and release by QP in EU member state was performed. Medvacon also remediated the Quality System in anticipation of an FDA PreApproval Inspection.

Parenteral Drug Product – Aseptic Operations

Medvacon is currently supporting a client's new parenteral drug development project at a CMO site. Medvacon's involvement includes quality assessment of the aseptic facility, review of manufacturing procedures, review of aseptic

gowning procedures and personnel training, review of environmental monitoring procedures and data, review of media fill batch record, interventions and execution, and review of process validation for the new drug product.

QUALITY SYSTEM IMPLEMENTATION (QMS)

Quality Management Systems for the pharmaceutical industry stem from key regulations that the FDA enforces such as 21 CFR Part 211. Under this regulation, a quality management systems definition would necessarily cover the concept of a quality control unit, which is responsible for overall quality management systems. The quality control unit is primarily responsible for documentation (procedures, SOPs, policies, etc.) and control of all documents that impact product quality and safety. In addition to 21 CFR Part 211, the FDA guidance called "Pharmaceutical cGMPs for 21st Century–A Risk-Based Approach" provides principles and standards that will help pharmaceutical companies establish an organizational QMS definition. This guidance offers a quality systems model and shows how manufacturers can comply fully with 21 CFR Part 211. The ICH Q10, a harmonized guidance for the pharmaceutical industry offers a model QMS based on ISO concepts and principles on Good Manufacturing Practices.

For medical device companies, the Quality System Regulation (21 CFR 820) offers a solid basis for a quality management systems. It is the primary FDA regulation for medical device companies. In as much as it helps manufacturers create their own organizational QMS definition, the regulation offers enough leeway for individual companies to define their priorities based on the device they are manufacturing. Most medical manufacturers also adhere to ISO 13485, which similarly provides a quality management systems definition. The FDA has harmonized QSR with ISO standards, making them complementary. Both QSR and ISO 13485 require the establishment of a quality management system that encompasses many quality processes, such as document control, training control, corrective action and preventive action (CAPA), and audit management processes.

Example Projects

IT Quality System Development

A Pharmaceutical company focused on developing small-molecule anti-cancer therapeutics targeting cancer cell metabolism via the growth factor pathway engaged Medvacon Life Sciences to evaluate their existing IT Policies and Procedures and develop an overarching IT Quality System, along with development of requisite documents. Medvacon Life Sciences developed sixty-four IT Polices, Procedures and Work Instructions which form the basis of their IT Quality System.

Pharmaceutical IT QMS

Medvacon Life Sciences was engaged by a pharmaceutical company focused on oncology drug research and development to implement an IT Quality Management System for their clinical activities. Medvacon Life Sciences developed the IT Quality Policy and assessed all clinical systems for compliance.

MasterControl QMS

Medvacon Life Sciences has partnered with MasterControl, a leading provider of Quality Management Systems in the life sciences market. Medvacon Life Sciences performs software quality assurance testing and validation of the QMS and works with client implementations providing validation, project management and implementation. Medvacon Life Sciences has been involved in the implementaiton and validation of over 50 QMS client installs.

PROGRAM & PROJECT MANAGEMENT (PM)

Project management consultancy services are necessary and critical to the success of complex projects (those that are high impact and time sensitive) within your organization. Medvacon Life Sciences' project management consultants utilize process, discipline, and leadership to break down functional silos, engage stakeholders, and ensure your initiatives are completed within budget, scope, and schedule. You can begin a project with us, from initiation to completion or if your project is missing milestones or is lacking momentum we will deploy project management consultants to get your project back on track.

Example Projects

Pharmaceutical Rapid Project Startup

A Pharmaceutical company focused on pain management engaged Medvacon Life Sciences to conduct a rapid project startup for a multi-year tech transfer project for a key product. Using Progressive Elaboration, we took the full core team through a series of workshops that result in a fully planned project in two days. The results of the workshops were a comprehensive project plan including: Project Objective, Scope (Deliverables, Measures, Exclusions), Work Breakdown Structure, Responsibility Matrix, Schedule, Issues, Risks and Assumptions. All of these in a Gantt chart that shows the full schedule with notes attached showing all the risks, issues, and assumptions on the relevant tasks.

Project Financial Controls

Medvacon Life Sciences was engaged by a biopharmaceutical company focused on development and manufacturing of vaccines to provide project financial controls for a $400M vaccine facility construction project. Medvacon Life Sciences' Sr. Financial Project Controller & Financial Consultant reside onsite at the client and is responsible to: Lead the cross functional team assigned to Project Controls for the Engineering, Validation, and Operations related activities; Deliver the monthly Financial forecast; Further enhance and maintain the Project Forecast File; Develop and Manage the Risk Allowance File and Simulate risk allocations through Monte Carlo Analysis; Collaborate with the Construction management cost controller to ensure alignment in all reporting; Manage the Invoice and Bank Processes; Provide Aggregated Forecast to the Site Leadership; Develop the Communication Plan Purchase Order and Manage the Purchase Order process.

Tech Transfer Project Management

Medvacon Life Sciences was engaged by a pharmaceutical company to provide senior level program and project management for a multi-year tech transfer for a key product involving international coordination. Medvacon Life Sciences' Sr. Project Manager performed a Gap Analysis, Developed a Quality Plan, Provided Validation Master Plan Support, Refined and Manages a detailed Program Schedule Gantt Chart, Refined and Manages a Resource Plan with

RACI Matrix and conducted Risk Analysis and Mitigation Planning in addition to providing overarching Project Management.

REGULATORY COMPLIANCE (RC)

Medvacon Life Sciences provides a host of Regulatory Compliance consulting Services. Our Regulatory experts possess comprehensive knowledge of the Code of Federal Regulations and are prepared to assist you with your Regulatory Compliance Consulting needs. Our experience provides us with a unique understanding of the impact of federal regulations on your business operations. Our experts can provide in-depth assessments of your company's compliance levels and help get products to market quickly.

Medvacon Life Sciences offers a comprehensive menu of cost-effective solutions and helps our clients traverse the landscape of regulatory requirements and language and to mitigate the risks associated with operating in a regulated industry.

Investigating the cause of a quality failure or other production problem is something that all pharmaceutical companies must do, some more frequently than others. The more comprehensive and structured the investigation process is, the more effective it will be. While CAPA is handled differently at many pharmaceutical manufacturers, best practices for handling complaints and investigations revolve around certain core activities, a basic process and, more often than not, some enabling technology. Medvacon Life Sciences' Team of Quality Investigation and CAPA experts can assist your company in achieving Quality Investigation compliance.

Example Projects

Regulatory Compliance CE Mark Submission Drug Dossier Development

A client developing drug-eluting bioresorbable coronary scaffolds for the treatment of cardiovascular disease, the leading cause of death worldwide, engaged Medvacon Life Sciences to assist the firm in preparing a drug dossier required for CE Submission in Europe. Specifically, Medvacon Life Sciences' scope of services was to: Review program and current status; Review requirements for a drug module going to MHRA; Organize communication and next steps; Set initial assignments and requirements for a given section; Update work remaining and subsequent planning; Upon completion of the module provide final review and comments to client team.

Combination Medical Device - Pharmaceutical Regulatory Compliance Consulting

Medvacon Life Sciences' client is a combination Pharmaceutical- Medical Device manufacturer engaged in emergency care treatment options into the hands of military and civilian defenders for more than 50 years. Our client is committed to help defend against critical, time-sensitive, life-or-death situations by providing medical countermeasures to the

United States Department of Defense, Emergency Medical Services, Homeland Security, and more than 30 nations around the world. Client engaged Medvacon Life Sciences to assist in Root Cause Analysis and remediation of FDA findings.

Regulatory Compliance Annual Report Development

Medvacon Life Sciences' client is a pharmaceutical company whose mission is not one of drug discovery but rather that of acquisition and commercialization of prescription products that will satisfy unmet clinical needs in specialty therapeutic areas. This "virtual company" outsources the manufacture, pharmaceutical development, packaging and testing of their products. Medvacon Life Sciences was enlisted to provide Regulatory Compliance assistance to support the development of Annual Reports for submission to the client's eCTD submission vendor. Specifically Medvacon Life Sciences reviewed submission documents and prior Annual Reports to assemble the submission materials and prepare the submission form.

Combination Medical Device - Pharmaceutical Regulatory Compliance Consulting

A combination Pharmaceutical-Medical Device manufacturer engaged in emergency care treatment options into the hands of military and civilian defenders engaged Medvacon Life Sciences to provide R&D support services for the development of new products as well as the improvement of existing auto-injector design.

Biopharmaceutical Regulatory CMC Services Consulting

A biopharmaceutical company specializing in applying deuterium chemistry to known molecules to create novel therapies with the potential for improved safety and efficacy profiles engaged Medvacon Life Sciences in the area of Regulatory Compliance Consulting. Client enlisted Medvacon Life Sciences to assist in bringing their product from development to market. Specifically Medvacon Life Sciences provided assistance with ensuring regulatory requirements were addressed and specifically ensure all elements of the CMC section were accurately represented. The product received FDA approval and Medvacon Life Sciences remains engaged overseeing CMC and Clinical Supply activities.

cGMP, IT, SUPPLIER & MOCK FDA AUDITS AND INSPECTIONS

Whatever your company's role in the life sciences supply chain – whether it is as a supplier, manufacturer or pharmaceutical, medical device or biotech company – demonstrating Good Manufacturing Practice (GMP) is key to securing customer trust, building your reputation and growing your business. A GMP audit from Medvacon Life Sciences will show that you are meeting customer and consumer expectations and working to ensure the quality and safety of your products.

Pharmaceuticals, Medical Devices and Biologics must be produced consistently and must be strictly controlled to meet both national and international standards appropriate for their intended use. Strict regulatory requirements must be met including those specified by US Food and Drug Administration (FDA) or UK Medicines and Healthcare Products Regulatory Authority (MHRA).

Medvacon Life Sciences' auditing team offers Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) audit services helping our clients to ensure that all relevant regulatory requirements (FDA, NF, MHRA) are met. We provide auditing solutions for all types of pharmaceutical products such as active pharmaceutical ingredients (APIs), drug products, excipients, over-the-counter products, vaccines and vitamins. Medvacon Life Sciences can add value to your business by helping you to achieve or maintain regulatory compliance for equipment, facilities, utilities, processes and process installations. Our global network of experienced auditors are available to conduct audits supporting the entire manufacturing supply chain.

Example Projects

cGMP & Quality Audit - Contract Manufacturing & Contract Laboratory

Medvacon Life Sciences' client is a pharmaceutical company whose mission is not one of drug discovery but rather that of acquisition and commercialization of prescription products that will satisfy unmet clinical needs in specialty therapeutic areas. This "virtual company" outsources the manufacture, pharmaceutical development, packaging and testing of their products. Client has engaged Medvacon to provide cGMP & Quality Audits for one of their Contract Manufacturing Organizations (CMO) who also packages their product and one of their Quality Control testing Laboratories, both located in New England.

cGMP & Quality Audit - Contract Manufacturing & Contract Laboratory

Medvacon Life Sciences' client a CMO is a contract manufacturing organization that specializes in the formulation development and commercial services for oral solid dosage products. As part of the client's continuing dedication to excellence, they identified the need to engage an Medvacon Life Sciences to support the internal audit of their quality organization in support of maintaining a strong GMP compliant organization. Medvacon Life Sciences performed a high level audit of the critical quality functions within the CMO's quality organization. A report was developed and issued and presented to the client. The client engaged Medvacon Life Sciences to conduct facility wide cGMP training for all facets of their staff.

cGMP & Quality Audit - API Supplier, Contract Laboratory & API Storage Warehouse

Medvacon Life Sciences' client is a virtual pharmaceutical company and outsources the manufacture, pharmaceutical development, packaging, warehousing, distribution and testing of their products. The client has engaged Medvacon to provide a cGMP & Quality Audit for one of their Active Pharmaceutical Ingredient (API) manufacturers in CO, another cGMP audit for their contract laboratory located in WI, and the third for their API storage warehouse located in IA.

Clinical IT Systems cGMP & Quality Audits

Medvacon Life Sciences' client, a fully integrated oncology drug research and development company with expertise in drug discovery, crystallography, medicinal chemistry, preclinical development, pharmacology, pharmaceutical development, CMC (chemistry, manufacturing, and control), global clinical trials, and regulatory affairs, engaged Medvacon to conduct IT CSV/GMP Audits of their clinical system suppliers. Medvacon Life Sciences' Auditor works in conjunction with the clients internal Quality Department to jointly audit client's suppliers on an ongoing basis. Medvacon prepares the audit agenda, conducts the onsite IT CSV/GMP audits, conducts daily closeout meetings with client, and prepares and delivers the audit reports to our client.

CSV & cGMP Audit of Hosting Systems Provider

Medvacon Life Sciences' client identified the need to audit their hosting service provider, who provides the hosting services for their Trackwise quality documentation management system. The hosting service provider was last audited by the client in 2015. As part of the ongoing effort to maintain quality systems in a state of documented compliance, client has engaged Medvacon Life Sciences to perform the Computer System Validation (CSV) and GMP audit of hosting provider with lat two location, one in NJ and the other in VA. This client has a specific auditing SOP to be followed. Medvacon Life Sciences' auditor conducted the following scope: Prepare Audit agenda: Conduct Audit preparation activities; Perform on site CSV/GMP audits of the hosting service provider; Report critical observations to client at daily closeout meeting; Conduct Client Debrief Meeting, Executive Summary and initial observations preparation; Develop Audit Report including observations; Prepare Audit Result letters and CAPA Request for submission to vendor; Issue Vendor Audit Certificate; Conduct CAPA review and Follow-up Discussions.

TECH TRANSFER PROJECT MANAGEMENT

A technology transfer takes place when a pharmaceutical company wants to change from an existing manufacturing site to a new manufacturing site. Medvacon Life Sciences helps our clients by providing senior level pharmaceutical technology transfer experts to lead each technology transfer project. These projects are multi-year in duration, which is why it is critical to have onsite support for the duration of the project.

Example Projects

Tech Transfer Consulting: Laboratory, Manufacturing and CMO

Medvacon Life Sciences was engaged in a multifaceted compliance consulting initiative. Client had just completed Phase III

Clinical Trials for a drug that addresses unmet medical needs in hyperkinetic movement disorders, and engaged Medvacon Life Sciences for overall compliance assistance with commercialization of the product. Medvacon Life Sciences provided compliance expertise to the client and their Contract Manufacturing Organization (CMO) with specific focus in the area of Process Validation, Equipment Qualification, Cleaning Validation, Tech-Transfer, Laboratory instrument qualification, and overall compliance assistance.

cGMP & Quality Audit - API Supplier, Contract Laboratory & API Storage Warehouse

Medvacon Life Sciences was engaged by a market leader in transdermal therapeutic systems (TTS) and oral thin films (OTF) to provide assistance with Tech Transfer. Client enlisted Medvacon Life Sciences to provide consulting services, specifically to analyze data and acceptance criteria associated with the technical transfer of their TTS for treatment of Parkinson's disease and moderate-to-severe primary restless leg syndrome, into the client's NJ manufacturing site.

CSV & cGMP Audit of Hosting Systems Provider

Medvacon Life Sciences was engaged by a pharmaceutical company to provide senior level program and project management for a multi-year tech transfer for a key product involving international coordination. Medvacon Life Sciences' Sr. Project Manager performed a Gap Analysis, Developed a Quality Plan, Provided Validation Master Plan Support, Refined and Managed a detailed Program Schedule Gantt Chart, Refined and Managed a Resource Plan with RACI Matrix and conducted Risk Analysis and Mitigation Planning in addition to providing overarching Project Management.

CAPA, DEVIATION & NON-CONFORMANCE INVESTIGATIONS

Medvacon Life Sciences delivers rigorous and comprehensive CAPA and Deviation Investigation and Closeout services that are designed to help reduce the overall cost of compliance for Life Sciences organizations.

When manufacturing pharmaceutical products, unexpected events can occur, for instance during production, analysis, transport, storage or even during the qualification and/or calibration of equipment. In the pharmaceutical industry these events are called deviations or non-conformances. Deviations could have a negative effect on the quality of the pharmaceutical products and could even result in a recall of the products. Furthermore, these deviations could be an indication that the quality system is functioning sub-optimally.

For these reasons, it is of the utmost importance to investigate these deviations. In such an investigation the following aspects are essential:

- Root cause analysis, to determine why the deviation occurred
- Impact assessment, to determine the (possible) consequences of the deviation
- Define corrective and preventive actions (CAPA), to be sure that correct actions were taken to immediately reduce the impact of the deviation, and to prevent the deviation from re-occurring

The FDA Expects:

Quality Systems staff are effectively integrated into manufacturing and involved in non-conformance investigations.

- The investigation, conclusion and follow-up must be documented
- Any deviation from the written procedures recorded and justified
- Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records), or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. (211.192)
- The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and follow up. (211.192)

We offer our clients an FDA Compliant, comprehensive CAPA - Deviation - Non-Conformance Investigation and Closeout solution.

Example Projects

Aseptic Combination Product Manufacturing Client

Medvacon Life Sciences was engaged by an Aseptic Combination Product client to conduct investigations into deviations and non-conformance's in the aseptic manufacturing suites used to produce the combination product. Medvacon Life Sciences deployed a team of experts to conduct the investigations and assist this client in meeting stringent FDA commitment timelines. In performing these activities Medvacon Life Sciences was engaged by the client to resolve a highly technical issue with the combination product mechanical components and successfully identified the issue and implemented a change to the process. While the FDA commitment timelines were met, the team remains in place to assist this client with ongoing investigations and closeouts.

Contract Manufacturer - Pharmaceuticals

Medvacon Life Sciences was engaged by a Contract Manufacturer to assist with investigation and close out of self-reported open deviations and CAPA's in several functional areas within the manufacturing site. Medvacon Life Sciences deployed a team and assigned a lead to each functional area to drive the investigations and closeouts to completion. The Medvacon Life Sciences team leads worked closely with each other and client leadership and were able to identify common root causes that impacted various functional areas. Corrective actions were put in place to prevent future occurrences. The Medvacon Life Sciences team members followed this approach: conducted root cause analysis, to determine why the deviation occurred; conducted an impact assessment, to determine the (possible) consequences of the deviation; defined corrective and preventive

actions (CAPA), to be sure that correct actions were taken to immediately reduce the impact of the deviation, and to prevent the deviation from re-occurring.

FDA Inspection Readiness (IR) Form 483 & Warning Letter Remediation

Inspection Readiness (IR) is a process of getting ready for an inspection by a regulatory authority (such as FDA), which is conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the clinical trial. Every pharmaceutical company is responsible for inspection readiness through providing the training to employees and ensuring their understanding and application of policies, standards, and procedures. Pharma organizations should allocate the right number of qualified resources to assure that inspection teams are in place to manage activities before, during, and after inspections. Clinical Operation Managers are traditionally driving the IR activities for the given clinical study with Quality Assurance (QA) support. Manufacturing/CMC Inspection Readiness is usually covered by separate QA GMP group. In both cases, IR is a cross-functional effort.

Surviving an FDA inspection is all about managing risk—understanding your weaknesses, anticipating how investigators will perceive them and preparing your staff to respond. The human factor can make or break an inspection and may present the biggest risk of all if you are not fully prepared. You can't completely control what your employees will say, but careful consideration and preparation will minimize problems. Medvacon Life Sciences can assist in preparing your organization for the inspection. Medvacon Life Sciences delivers rigorous and comprehensive **FDA Inspection Readiness and FDA remediation services** that are designed to provide cost efficient resolution of FDA readiness and remediation activities.

An **FDA 483 or Warning Letter** often only addresses a small portion of the true deficiencies in the quality system. Medvacon Life Sciences can help determine the actual depth and breadth of the quality system deficiencies via a comprehensive FDA Compliance GAP Assessment. The GAP Assessment includes preforming baseline audits, and developing a remediation plan to address all of the deficiencies and bring the Quality System or specific sub-section into compliance. For clients that already know the areas that need attention, Medvacon Life Sciences' staff of compliance experts are at the ready to tackle those specific areas.

Example Projects

Warning Letter Remediation - Aseptic Combination Product Manufacturing Client

Medvacon Life Sciences was engaged by an Aseptic Combination Product client in response to an FDA Warning letter to conduct investigations into deviations and non-conformances in the aseptic manufacturing suites used to produce the combination product. Medvacon Life Sciences deployed a team of experts to conduct the investigations and assist this client in meeting stringent FDA commitment timelines. In performing these activities, Medvacon Life Sciences was engaged by the client to resolve a highly technical issue with the combination product mechanical components; Medvacon successfully identified the issue and implemented a change to the process. While the FDA commitment timelines were met, the team remains in place to assist this client with ongoing investigations and closeouts and Quality Systems Consulting Services.

Pre-Approval Inspection (PAI) Readiness - Pharmaceuticals

Medvacon Life Sciences was engaged by a pharmaceutical client to assess and remediate their Quality System in anticipation of an FDA Pre-Approval Inspection. Medvacon deployed a team of experts at the client site to assess and identify existing GAPs. Once the initiative of identifying the GAPs was complete, and with client buy-in on the approach, the Medvacon Life Sciences team put a plan in place to remediate the identified GAPs. The plan included a holistic remediation of the entire quality system with a focus on automation of the quality system and ensuring compliance of that initiative from a CSV and 21 CFR Part 11 perspective.

DATA INTEGRITY

DEFINITION: "Data Integrity refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA)" - FDA Guidance Data Integrity and Compliance With Drug cGMP

In recent years, FDA has increasingly observed cGMP violations involving data integrity during cGMP inspections. This is troubling because ensuring data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health. These data integrity-related cGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. The underlying premise in §§ 210.1 and 212.2 is that cGMP sets forth minimum requirements to assure that drugs meet the standards of the FD&C Act regarding safety, identity, strength, quality, and purity. Requirements with respect to data integrity in parts 211 and 212 include, among other things:

- § 211.68 (requiring that "backup data are exact and complete" and "secure from alteration, inadvertent erasures, or loss" and that "output from the computer… be checked for accuracy").
- § 212.110(b) (requiring that data be "stored to prevent deterioration or loss").
- §§ 211.100 and 211.160 (requiring that certain activities be "documented at the time of performance" and that laboratory controls be "scientifically sound").
- § 211.180 (requiring that records be retained as "original records," or "true copies," or other "accurate reproductions of the original records").
- §§ 211.188, 211.194, and 212.60(g) (requiring "complete information," "complete data derived from all tests," "complete record of all data," and "complete records of all tests performed").
- §§ 211.22, 211.192, and 211.194(a) (requiring that production and control records be "reviewed" and that laboratory records be "reviewed for accuracy, completeness, and compliance with established standards").
- §§ 211.182, 211.186(a), 211.188(b)(11), and 211.194(a)(8) (requiring that records be "checked," "verified," or "reviewed").

When considering how to meet many of these regulatory requirements, it may be useful to ask the following questions:

- Are controls in place to ensure that data is complete?
- Are activities documented at the time of performance?
- Are activities attributable to a specific individual?
- Can only authorized individuals make changes to records?
- Is there a record of changes to data?
- Are records reviewed for accuracy, completeness, and compliance with established standards?

- Are data maintained securely from data creation through disposition after the record's retention period?

What is ALCOA? The five data integrity attributes as defined by the FDA:

- **Attributable**. Data must be stored so that it can be connected to the individual who produced it. Every piece of data entered into the record must be fully traceable in time.
- **Legible**. Data must be traceable, permanent, readable, and understandable by anyone using the record. This also applies to any metadata attached to the record.
- **Contemporaneous**. Data must be fully documented at the time they are generated or acquired.
- **Original**. Data must be the original record or in a certified copy. The data record should include the first data entered and all successive data entries required to fully understand the data.
- **Accurate**. Data must be correct, truthful, complete, valid and reliable.

Medvacon Life Sciences delivers leading Data Integrity and Computer System Validation services that are designed to help reduce the overall cost of compliance for Life Sciences organizations. We offer our clients comprehensive services, including leadership and a range of strategic solutions and tactical services that provide cost-effective and comprehensive compliance and validation. The Medvacon Life Sciences team of highly-qualified consultants can deliver a broad suite of solutions in areas of computer systems validation, infrastructure qualification, IT Quality Management, and process improvement.

- Risk-Based Computer System Validation
- Software QA and User Acceptance Testing
- Software Vendor Audits
- Gap Assessments and Remediation
- SDLC Methodology Development
- SOP Development
- Project Management
- 21 CFR Part 11 Compliance and Assessments
- IT Policies and Procedure Development

Computer Software Validation is a formalized, documented process for testing computer software and systems, required by 21 CFR 11.10(a) and Annex 11, Section 4. The FDA and other regulatory bodies require validation to demonstrate that computer systems are in compliance with all regulations for electronic data management systems. Failure to validate systems is one of the leading reasons a business is issued a 483. Medvacon Life Sciences can validate all of your software, databases, spreadsheets, and computer systems, and develop the appropriate documentation for all phases of the software life cycle. We have written and executed validation packages for systems of all sizes. We can provide any level of service required, from executing test scripts generated from your existing specifications to writing the entire validation package. Medvacon Life Sciences will follow your existing validation procedures or provide your company with validation standards. Our validation methodology ensures validation deliverables that are in line with industry standards & best practices, focus resources towards the most critical system functions, and complete the validation projects efficiently.

Example Projects

Lab Systems Software Implementation & Validation

Medvacon Life Sciences' Pharmaceutical client planned on deploying Waters Empower 3 Chromatography software in their facilities for use with approximately 30-35 HPLCs. To ensure compliance with current Good Manufacturing Procedures Pharmaceutical Company engaged Medvacon Life Sciences to perform Computer System Validation activities for the implementation. Medvacon Life Sciences' activities included the following scope of work: Prepare the User and Functional Requirements (URS/FRS) and the Traceability Matrix (TM);

Review Waters vendor software testing documentation per Detailed Design Specifications (DDS) including software modules, graphics, HMI components and batch reports; Review Configuration Specification/DDS documents against requirements; Author IOQ leveraging the vendor IOQs for the Waters Empower 3 Chromatography Data Software; Execute IOQ and prepare the IOQ summary report; Author PQ for the live environment; Execute PQ for the live environment; prepare PQ for summary report; Author data transfer and integrity testing protocol for transfer of data from Empower 2 to Empower 3; Execute data transfer and integrity testing protocol, prepare Summary Report; Prepare Validation Summary Report and final Traceability Matrix; Support deviation closure; Support developing SOP's; Generation of VSR; documentation; Provide Project Oversight and Management (PM)

21 CFR Part 11 & CSV Methodology Assessment

Medvacon Life Sciences was engaged in a multifaceted compliance consulting initiative. Medvacon Life Sciences provided professional consulting services in the area of 21 CFR Part 11 compliance as well as requisite requirements such as System Development Life Cycle (SDLC) and Validation. Medvacon Life Sciences specifically provided: written 21 CFR Part 11 compliance assessment reports for the five types of computer controlled test equipment at client; written assessment report of the client site IT Policies & Procedures to ensure 21 CFR Part 11 compliance controls; written assessment report of site IT Policies & Procedures governing their System Development Life Cycle (SDLC) methodology required for developing software used in a GxP environment; Validation and 21 CFR Part 11 compliance consulting services specific to client's in-house developed MS Access based test-data collection and reporting system.

FDA LIMS Validation and SOP Consulting

Medvacon Life Sciences was engaged by our partner to assist FDA lab staff by identifying where in their SOPs updates for LIMS need to be made far in advance of the lab implementation. Medvacon Life Sciences ensured that the LIMS-relevant SOPs from the labs and QMS staff were available. This included instrument qualification, operational qualification, and performance qualification (IQ/OQ/PQ).

QMS Software Quality Assurance & Validation

An industry leader in Quality Management Software has engaged Medvacon Life Sciences in a multitude of ongoing CSV, SQA and PM activities. Medvacon Life Sciences has a dedicated team that prepares and executes PQ's for QMS providers' client implementations. Medvacon Life Sciences has another dedicated team that conducts full SQA and validation of QMS providers' quarterly software releases.

PDMA Sample System Validation

Medvacon Life Sciences' client that provides Prescription Drug Marketing Act (PDMA) sample compliance services engaged Medvacon Life Sciences to validate their acknowledgement of delivery tracking system. Medvacon Life Sciences developed the project plan, Validation Plan, reviewed the URS and FRS, and developed the IQ/OQ and PQ. Medvacon Life Sciences executed the protocols and developed the validation final report.

Pharmaceutical IT Policies & Procedures Development

A Pharmaceutical company focused on developing small-molecule anti-cancer therapeutics engaged Medvacon Life Sciences to evaluate their existing IT Policies and Procedures and develop an overarching IT Quality System,

along with development of requisite documents. Medvacon Life Sciences developed sixty-four IT Polices, Procedures and Work Instructions which form the basis of their IT Quality System.

cGMP AND PROJECT MANAGEMENT TRAINING

Medvacon Life Sciences offers training in the area of cGMP compliance, and Project Management and will custom tailor a compliance course for your organization. Good Manufacturing Practice regulations, which have the force of law, require that manufacturers, processors, and packagers of medicinal products take proactive steps to ensure that their products are safe, pure, and effective. cGMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. Personnel involved in cGMP must have documented training of current Good Manufacturing Practices (cGMP) training. This training will focus on the FDC Act and 21CFR federal regulations as applied to cGMP and provide an overview of the US FDA regulations for compliance.

Medvacon Life Sciences' cGMP Course covers the requirements for establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories within a pharmaceutical production environment. Participant involvement is encouraged through the use of practical exercises, quizzes, and examples from actual companies.

Medvacon Life Sciences' Project Management Training spans a wide variety of areas and if the specific courses below do not fit your need we are happy to customize a program that fits your organizations needs.

- An **Executive Briefing** consists of a two to four-hour session with the senior staff training them on the importance of Project Management to the organization. They will learn the role they need to play during the Maturation of Project Management, the way to convert high-level strategies to Project Objectives, the methodology of Project Prioritization and the way to effectively run the Phase Gate Sessions.
- **Project Management Training sessions** are two full days of classroom training designed to teach Project Managers and Team Members how to effectively manage projects. Through a combination of lecture and real-life client project workshops, the participants will learn how to effectively plan and execute projects, run efficient status meetings, deal with authority issues and people management, deal with project problems and manage change control. This class is workshop-intensive where the students will be broken up into groups of 4 - 6 and will spend the two days using the tools they learn to progressively elaborate one of their real projects from scope to objective, charter to Work Breakdown Structure, Responsibility Matrix to Schedule and Budget until they have the entire project in their hands. We use large charts and wet-erase markers to ensure the entire team is involved in the workshops. Questions and discussions are encouraged. Our instructor involves everyone in the class through his use of stories and examples, bringing the lessons to life in an entertaining, humorous and, ultimately, lasting fashion. You will walk out of class with the tools you need to plan and execute your projects with efficiency and confidence.
- **Rapid Project Startups** are one to two day events where the entire project team is assembled and the project is run through the planning phase while being facilitated by the instructor. This is an excellent way to reinforce the training received in the above two courses while giving key projects a head-start toward completion. The instructor will lead the team through the steps of Background, Objective, Scope, Work Breakdown Structure, Responsibility

Matrix, Schedule and Budget to arrive at a fully developed plan in one or two days depending upon the size of the project.

- **Prioritization Sessions** are an assembly of the Steering Committee during which the business unit's projects are Inventoried, Categorized, Prioritized within categories, then Prioritized across categories to arrive at a single, prioritized list of projects according to business importance. Future Prioritization Sessions eliminate completed projects, prioritize newly authorized projects, reprioritize the list and spend leftover time reviewing projects going through phase gates and projects that have been working without reviews for too long.
- A **Project Management Guide** is a document customized by a team of client employees assisted by the instructor based on templates he provided that defines the methodology used to manage projects. This becomes the reference guide for those who are tasked as Project Managers and Team Members by delineating their roles, laying out the templates they will be using, explaining the approval and gating processes, showing how resourcing projects works and defining the roles played by all team members in the successful completion of the project. This guide defines the role of the Project Management Office, (PMO) and is maintained in future, along with all templates and the resourcing spreadsheets by the PMO. The templates are provided free along with the acceptance of 10 days of facilitation time in the process of customizing this guide.

Example Projects

Project Management Training - Pharmaceutical

A Pharmaceutical company identified the need for support in developing their internal project management organization in order to support ongoing efficient and effective operation of project teams. Medvacon Life Sciences delivered the Executive Briefing, the Two-Day Project Management Training session on the East and West Coasts, and conducted several Rapid Project Startups. The client was delighted and has scheduled additional Rapid Project Startups at another of their sites.

cGMP/Compliance Training - API Manufacturer

During Medvacon Life Sciences' onsite CSV initiative, the client identified the need for 3rd party Compliance training assistance of operational and administrative personnel; this to increase staff awareness of quality assurance and compliance standards in a GMP environment. Subsequent discussions with the Quality Mgr identified a continued goal of the client maintaining a strong GMP-compliant organization via Compliance training course(s). This training provided Quality, Production, Maintenance, Operational and other personnel, (who possess varying levels of knowledge and experience); the opportunity to refresh and expand their knowledge and applied skills using an in-depth and compliant applicable approach in a GMP manufacturing facility. The Training Program was an immersive onsite engagement.

cGMP/Compliance Training - CMO

Following a 3rd party audit conducted onsite by Medvacon Life Sciences, the CMO's Associate Director of Quality requested additional training support of staff to increase awareness of quality assurance and compliance standards: "As part of the company's continuing education and commitment to excellence, the CMO has identified a need for Compliance Training of the Quality Team with a continued goal of maintaining a strong GMP-compliant organization via a training course for QA Compliance. This training is intended to provide QA Auditors and QA Management who have basic auditing knowledge and experience, the opportunity to refresh and expand their knowledge and applied skills using an in-depth and compliant applicable approach in a GMP CMO manufacturing facility." "In a fast-paced, multiple-shift, versatile work environment, the

overarching goal is to raise the proficiency and efficiency level of QA Auditors from passive, by-the-book checking of documentation / documents to an interactive and supportive Quality Department that can quickly evaluate issues or gaps, offer compliance guidance / recommendations/instructions with confidence while focusing on solutions that direct the work activities as needed to achieve work schedules, project tasks and meet business timelines, without compromise on compliance." Consequently; Medvacon Life Sciences developed and delivered the onsite two-day Training Program as an immersive engagement at the CMO facility.

M&A COMPLIANCE DUE DILIGENCE

Both in the private equity and trade buying space, regulatory change is the primary driver of volatility in the market. However, traditionally in M&A transactions, financial, legal and commercial considerations have taken precedence over regulatory considerations. Failure to perform robust regulatory / FDA Compliance due diligence is not an option in today's regulatory environment and can lead to unknown liabilities materializing after the deal.

The benefit Medvacon Life Sciences provides is very unique and the service we offer is critical during the due diligence phase. During this time, we conduct inspections and audits of the company's FDA regulated systems. This may include warehousing, manufacturing, packaging, distribution, supply chain, all supporting computer systems, Quality Management Systems, etc. The reason this work is so important is because many organizations ignore this area during the due diligence phase and then are surprised later when issues in the system are flawed and they have to pay six or seven figure fees to rectify the issues. This becomes especially critical (and more expensive) if these gaps are found during an FDA audit. By identifying these issues ahead of time the cost and impact of remediation could be factored into the offer placing the acquiring company in a better financial position. This approach and work also provides the company with a detailed report as to the critical issues that must be addressed. This initiative also serves another purpose; if the FDA does inspect, the fact that the issues were identified and plans were in place to remediate the issues, places the company in a more defensible position and provides it with time to address the items identified. In addition to conducting the assessment, Medvacon Life Sciences provides the expertise to help the organization remediate any gaps and achieve compliance.

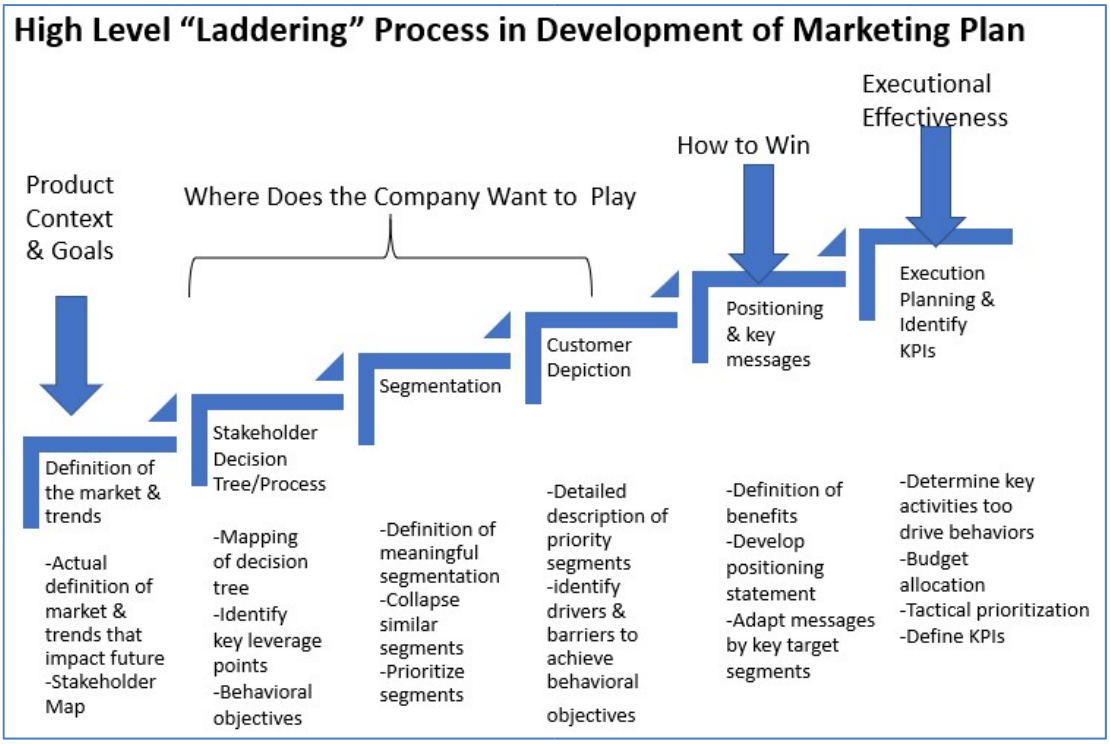
By ensuring a robust approach to regulatory due diligence, firms can gain a host of benefits. Throughout the process of an acquisition and while taking into consideration the factors mentioned above, firms should constantly reflect on whether their due diligence process (and the deal itself) facilitates:

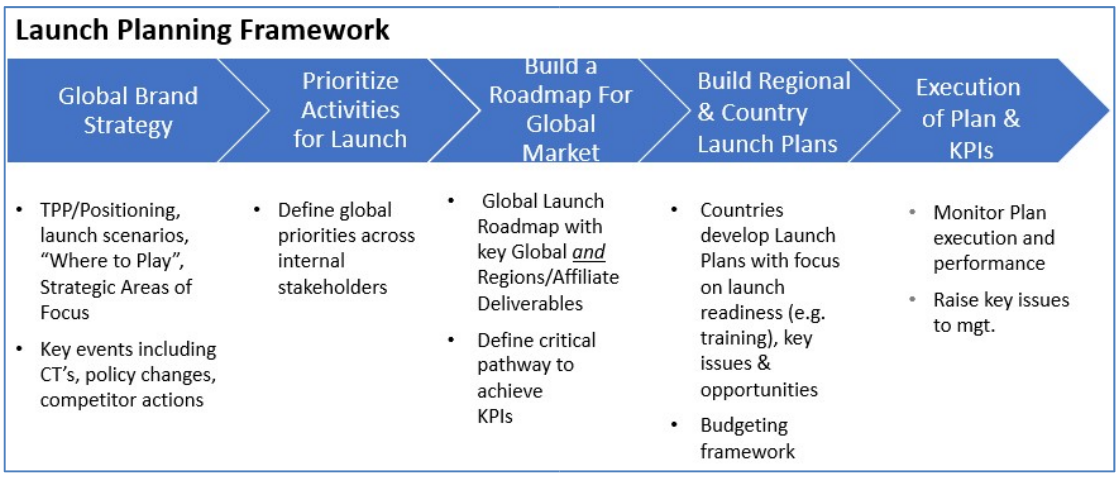
- **Regulatory approval** – approval of the transaction is of course the end goal, and robust due diligence can help achieve this
- **Effective risk analysis** – ensuring your process leaves no stone unturned will result in the highest level of assurance against future regulatory-related costs
- **The avoidance of fines** – through gaining a full understanding of what issue may exist and putting a plan in place to mitigate those issues, places the company in a much more defensible position for regulator inspection. Furthermore, after a transaction has taken place, acquiring firms may struggle to obtain restitution for any historic issues. Robust regulatory due diligence can help mitigate this
- **The preservation of reputation** – whether issues are uncovered that make a deal untenable, or a solvable issue presents itself, the acquiring firm can protect its reputation by either walking away or implementing a plan to solve regulatory issues as early as possible. The acquiring firm can also stipulate that issues are solved within the firm to be acquired before acquisition takes place
- **Pricing assurance** – issues identified by regulatory due diligence needn't always result in a transaction being blocked and, indeed, robust due diligence can provide the information a firm needs to negotiate a realistic price – one that reflects the cost of correcting any issues, for example

- **The understanding of best practice** – aligning the firm with regulatory expectations will help ensure compliance and help to drive best practice prior to completion of the deal

PRODUCT LAUNCH MARKETING PLAN DEVELOPMENT

Medvacon senior personnel have a successful track record of brand strategy, new product development, product launch, lifecycle management, sales execution, and profit optimization. Medvacon can assist with your product launch marketing plan development and implementaion.





If you would like to have an initial, no obligations, consultation with an expert to discuss your project, please feel free to contact us at 833-MEDVACO.

TALENT ACQUISITION ~ STAFFING SOLUTIONS

Experts hiring experts in industry specific positions

Why trust Medvacon Talent Acquisition to find your most valuable resources? Because we understand your business:

Consulting ~ Contract To Hire ~ Direct Placement

Medvacon Talent Acquisition is about Quality. When hiring needs increase, we're an extension of your business when the time is right. Medvacon Talent Acquisition will manage the sourcing, qualification and interview process and short-list industry experts who align with your business needs, company culture and career path. We maintain close relationships allowing us to keep a pulse on market trends, compensation analysis and identify business-critical talent. MEDVACON Life Sciences uses market intelligence to uncover misalignment between the required skills and the skills available in the market. Our Talent Acquisition team offers expertise across all markets allowing us to obtain buy-in at all levels.

We're your partner for tactical and strategic hiring initiatives for Independent Contributors to Executive Leadership.

- cGMP Validation
- CSV/Data Integrity
- Program/Project Management
- Regulatory Compliance
- Audit/Inspection Readiness
- CAPA/Remediation
- QMS
- IT Quality Management
- Process Improvement
- Quality Systems Implementation
- Risk Management
- Medical Device
- Manufacturing Process
- QA Positions

If you would like to have an initial, no obligations, consultation please feel free to contact Contact Cris Maroney, Sr. Director of Talent Acquisition to learn more: (973) 435-0942