Michael Tokarski
Professional Packaging Engineer (retired)

Summary

Highly focused engineer and technical manager with excellent skills in packaging, product and process development. Pivotal contributor on projects considered strategically significant and requiring leadership and problem solving skills for successful resolution. Experience with medical devices, pharmaceutical combination products and aseptic packaging in food environments. Subject matter expert on extruded polymers and laminations used in high barrier sterile packaging, thermoformed and injection molded containers and related packaging and integrity test methods. Broad understanding of materials qualifications and release procedures. Excellent communication and people skills.

Professional Highlights

Kinetic Concepts, Inc. San Antonio, TX (Now 3M) (Medical Devices - Surgical) 2009 to 2017
Principal Packaging Engineer

Negative pressure wound therapy (NPWT) devices are Class 2 medical devices. Basic responsibilities included process characterizations for heat sealing, package design, development and rollout, materials applications, sterile barrier, ship testing, validations, sterilization coordination, labeling, organization of BOM's, artworks and environmental compliance. Direct responsibility for packaging support to sites in San Antonio, Ireland, Belgium and Mexico (contract packaging).

Personally invited by the VP of Manufacturing Engineering to join the company to fill a gap where no packaging expertise had been in house for two years. Immediate focus was to affirm processes for sterile barrier packaging, ship testing (ASTM D4169) and validation. Because methods for implementing validations, ship testing and package development lacked clarity, defined and implemented processes and procedures to conform to recognized industry standards. Focus on validations (IOQ and PQ), DOE, and FMEA. Also aligned test procedures to ASTM methods

As part of a company-wide COGS reduction effort, identified $1.8MM in packaging savings opportunities - immediately implemented two projects valued at $600K in savings. Additional projects in queue for future delivery.

Interacted with Marketing teams on new products, process improvements to insure best packaging designs and applications for product.

Reviewed and upgraded processes and systems for sterile barrier testing. Prior to my arrival, test methods for sterile barrier were not well understood and testing at that time was being misapplied. Established and educated project teams in terms of the appropriate methods and statistical techniques needed for material and process characterizations, validations and ongoing production. Primary method of sterilization is gamma irradiation and therefore insured alignment of best packaging practices to this sterilization method.

Investigated and reviewed processes for FFS machines in Ireland facility where throughput and yields were low. Developed plans for key areas where processes improvements could be made. Result was improved performances for packaging automation.

Environmental gaps existed in terms of requirements for European packaging. Established consistency to EU Packaging Directive 94/62/EC. Developed a database for all packaging materials identified as the Essential Technical Requirements. Detailed descriptions of all components, heavy metals impacts, re-use and recovery paths to comply with the directive.

Directly supported the Global Labeling Team in terms of printing technologies for packaging materials and labeling. Drove consistency in terms of overlabels used such that specific materials were put in place to show tamper evidence and prevent product misbranding. Also supported efforts related print technologies (i.e. flexo and litho) to insure optimum print performance for graphics deployed. Interacted with Regulatory Affairs for all packaging related initiatives.

Vistakon, Division of Johnson & Johnson, Jacksonville, FL **(Contact lenses)** **2000 to 2009**
Manager of R&D Combination Products (2004 – 2009)
Manager of Packaging Development (2000 - 2009)

Successfully developed and delivered a new primary packaging system for a drug/device combination product. Integrated a uniquely designed thermoformed PETG clamshell tray as the product carrier with a multi-laminate foil pouch to achieve package integrity and a sterile barrier. Due to the sensitive nature of the product, worked closely with the microbiological subject matter expert to co-develop a near aseptic package assembly process and sealing system in a modified atmosphere (N2) for processing prior to sterilization. Worked closely with a gamma irradiation facility in terms of executing dose map studies and irradiation processing for the final product/package configuration. Developed and executed package integrity, peel strength, opening force and ship testing according to ISTA, ASTM and other similar methods to insure robust performance. Provided support to Regulatory Affairs for packaging related aspects of INDA submissions.

Drove the package development efforts for new contact lens drug products. For one drug concept, product to package interactions were encountered. Led the effort to identify alternative, non absorptive materials for use. Over 150 different polymers and coatings were evaluated in the effort to establish the proper packaging material configuration. Importantly, laminated barrier foils had to be concurrently redesigned and the package sealing processes revalidated. Potential resolutions were constrained by the fact the final solution could not alter the existing production equipment base. A total, systemic solution was identified and successfully implemented. Included in this effort was shelf life evaluation, performance testing of MVTR, O2TR and toxicology while complying with CFR211 and ICH guidelines.

Established a pharmaceutical infrastructure within the company which did not previously exist. Because the company had been purely a medical device manufacturer since the 1980's, a cultural shift was needed to accommodate the migration to a pharmaceutical environment. Personally championed the design, build, implementation and management of two certified pharmaceutical clean rooms necessary for combination product clinical production. Created the documentation infrastructure required for pharmaceuticals production to parallel that of medical devices. Identified, staffed and trained an entire new team of personnel to be skilled in the art of clinical pharmaceutical manufacture. Once the infrastructure was fully established, shifted focus to manage contact lens combination product production for phase 1 and 2 clinical trials. Also leveraged outside companies comprised of ex-FDA auditors as a means to assess the readiness of the newly established systems from a cGMP compliance perspective.

Successfully managed a solution to a packaging/stability problem that had plagued the company for multiple years. Specifically, accelerated stability could not be achieved because USP sterility methods were applied throughout the course of stability testing. To accelerate temperature for faster evaluation and turnaround meant testing at temperatures that coincidentally delivered partial microbial kill and nullifying the opportunity for an expedient stability turnaround. As a result, accelerated stability had been limited to 39°C. Applied a new method and successfully campaigned the FDA to permit USP sterility testing at baseline but then altered the sterility test method to use package integrity as a sterility indicating means. Once implemented, accelerated testing limits were removed, reducing the time in accelerated test queue from two years to six months and allowing new products to be delivered to the market faster.

Responsible for new package designs that were applied to new sterilization techniques beyond the traditional autoclaves used in the contact lens industry. Created new, high barrier material configurations to replace traditional foil laminates, resulting in visibly clear packages and lidstocks that also facilitated sterilization by alternate radiation sources. Defined shelf life and demonstrated superior MVTR and O2TR capability for these packages as well as conducted consumer testing to establish end user performance.

Created new package concepts for contact lens packages. Designs included modifications to the existing package system, evolutionary concepts for next generation packages and revolutionary concepts that moved contact lens packaging from passive containers to interactive devices. Created a solution for contact lens materials that had the propensity to stick to polymer packages. Additives had been used within the saline solution to compensate for this issue, but package surface research and design ultimately led to the identification of altered surface finishes as an alternative to solve the problem. Also identified additives to packaging materials to create opaque packages where product light sensitivity was an issue.

SIG Combibloc, Inc., Columbus, Ohio (Packaging and aseptic systems manufacturer) 1988 to 2000
Champion of Change/Manager of Global Projects (1998 – 2000)
Manager of Packaging Development/Quality (1995 – 1998)
Packaging Engineer/Senior Packaging Engineer (1988 – 1994)

Requested by the CEO to assume responsibility for a new, value added "easy open - easy pour" packaging feature (an injection molded closure) prematurely introduced into the market which jeopardized the business due to sub-standard performance. Reengineered several design flaws that originally resulted in component breakage that would have translated into consumer performance problems and a possible product recall. Through modification of design and materials, corrected all issues within 90 days and with no negative impact to the market opportunity. Working with the German parent company, developed and initiated test procedures for this product that did not previously exist in order to deliver a total global resolution. Also created a statistical model to validate the product.

Working directly for the President and CEO, re-engineered the process flows for all manufacturing, research and aseptic systems. Drove the company's new mission to focus the culture to one of operational excellence and realigned the strategic direction to that of being a cost effective supplier of packaging systems with fast and flawless delivery processes. Based on the foundations authored by Treacy and Wiersema in their book “The Discipline of Market Leaders”, redefined the corporate operating model to exemplify a streamlined supply chain, standardized and centrally planned operations, reliable management systems and creation of a culture that abhorred waste and rewarded efficiency.

Delivered a complete solution to a package integrity issue that had challenged the company for eight years. Sporadic package integrity issues were resulting in field sterility problems. Critical focus was placed on the aseptic process and related package interactions. Closure was attained when it was identified that the system interaction was the root cause of failure. Resolution achieved in eight months. Also led a multi-million dollar packaging capital equipment upgrade of high barrier laminate extrusion, rotogravure printing and finishing equipment. Worked as the strategic sourcing manager to transform the packaging raw material suppliers (polymers, paperboards and foils) into strategic partners.

Key player in reversing a corporate threat by executing technology for juice box and carton recycling on a national level. Actions were initiated due to the fact that the package became banned in the state of Maine and threatened the lifeline of the business. As technical expert for a special industry alliance, designed and installed recycling systems for poly coated paperboards which could be recycled by paper mills and plastics converters. Installations were made in a number of states. One particular effort initiated in Florida won national recognition.

Interacted with the Food Sciences Group on shelf life and product performance initiatives. Created a new, non foil laminate structure with high barrier capability as an alternative to traditional foils with the goal of maintaining extended shelf life while more closely aligning to a consumer friendly, recyclable container.

National Steel Corporation, Detroit, Michigan (Integrated steel producer) 1977 to 1988
Electrogalvanizing Plant Manager (1986 – 1988)
Project Engineer and Maintenance Manager (1982 – 1986) – National Steel Continued
Electrical Supervisor (1977 – 1982)

Managed the operation of a 100 person department responsible for production of electrogalvanized sheet steel. Directed activities related to production, planning and quality. Coordinated efforts related to operations optimization, system improvements and related process programs. Responsibility for throughput and yield management. Interacted with other key business areas, including Sales, Quality and R&D.

Key player on the technical team that successfully started the first wide width domestic electrogalvanizing line. Involved in all technical phases of this $150MM startup. Participated in the design and installation of automated and PLC controlled systems, power rectifiers, AC and DC controls and high voltage switchgear. Upon technical transfer to operation, became the department manager responsible for the daily electrical and mechanical preventive maintenance of the equipment and facility.

Education

- Florida College at Jacksonville, Jacksonville, Florida – Continuing Education in German, 2004 - 2006
- Wayne State University, Detroit, Michigan - Bachelors of Science, Electrical Engineering Technology, 1977
- Henry Ford College, Dearborn, Michigan - Associate of Science, Electrical Technology, 1975

Professional Affiliations

- Previous Member IoPP (Institute of Packaging Professionals)
  Certified Packaging Professional (CPP)
- Past Committee Chair – Packaging Sterilization Sub Committee
  IoPP Medical Device Packaging Technical Committee

Professional Skills and Achievements

- Foreign Language - German (fluent conversational)
- Patents Awarded: 13
- Additional Patent Applications Filed: 23

Personal Information

- Widowed, wife is Christine
- One child, Jason
- Citizenship: United States of America
- USA Passport Status: Valid

Professional Achievements

- US Patent: Tear Away Container Top
  - Patents 6,766,941; 6,419,152; 6,241,646; 6,098,874
- US Patent: Container Closure Apparatus
  - Patent 6,244,503
- US Patent: Push Tab Hinge For A Container Closure Apparatus
  - Patents 5,992,734; 5,823,420; 5,639,018
- US Patent: Method Of Preparing Paperboard Food And Beverage Containers For Recycling
  - Patent 5,315,923
- US Patent: Screw Cap Package For Contact Lenses
  - Patent 7,562,768
- US Patent Application: Ophthalmic Lens Package with Deformable Bottom
  - Patent application number 20090139879
- US Patent Application: Contact Lens Package
  - Patent application number 20080105569
- US Patent Application: Contact lens Package
  - Patent application number 20080060950
- US Patent Application: Snap and Lift Package For Contact Lenses
  - Patent application number 20080023445
- US Patent Application: Package Mold Combination
  - Patent application number 20070257387
- US Patent Application: Interconnecting Contact Lens Package
  - Patent application number 20070199936
- US Patent Application: Contact Lens Package and Applicator
  - Patent application number 20070199831

- US Patent Application: Ophthalmic Lens Package With Frangible Pouch
    - Patent application number 20070102305
- US Patent Application: Contact Lens Package (Snap and Elevating Lift)
    - Patent application number 20070089998
- US Patent Application: Ophthalmic Lens Package With Internal Drainage Member
    - Patent application number 20060213784
- US Patent Application: Ophthalmic Lens Package (Clamshell with Absorbent Holder)
    - Patent application number 20060213783
- US Patent Application: Contact Lens Package (Multi-Lens Holder)
    - Patent application number 20060201103
- US Patent Application: Contact Lens Package (Flexible Peel)
    - Patent application number 20060054514
- US Patent Application: Contact Lens Package With Additives For Light Barrier Protection
    - Patent application number 20050205451
- US Patent Application: Contact Lens Package Containing Additives
    - Patent application number 20050006255
- US Patent Application: Contact Lens Package With Roughened Surface To Eliminate Sticking
    - Patent application number 20040031701
- US Patent Application: Contact Lens Package With Roughened Surface To Eliminate Sticking
    - Patent application number 20040004008