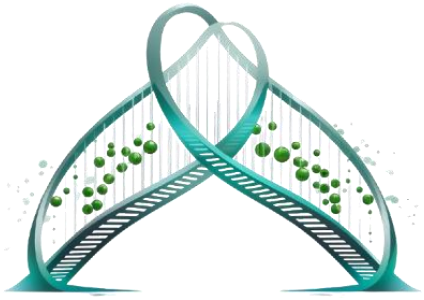

Biotech Bridge Media
Bridging the Gap Through Effective Content

QUICK GUIDE: REGULATORY-INTEGRATED MARKET RESEARCH FOR LIFE SCIENCES

Abstract: In life sciences, market research isn't just about customer preferences—it's a strategic tool that can make or break your product launch. This quick guide introduces the Regulatory-Integrated Market Research (RIMR) Framework, a step-by-step approach that aligns customer insight with regulatory strategy. By embedding FDA, CE-IVDR, and ISO 13485 checkpoints directly into the discovery phase, this guide ensures your market validation efforts lead to faster approvals, smarter positioning, and de-risked commercialization.

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Research with Regulatory Intelligence:
A Dual Mandate for Life Sciences Products

In regulated industries like diagnostics, medical devices, and biotech, product teams must think beyond traditional market research. It's no longer enough to validate need—you must **simultaneously validate regulatory feasibility**. That's where the RIMR framework comes in. It helps teams merge user insight, competitive analysis, and market dynamics with **FDA, EU MDR/IVDR**, and **QMS** alignment—**from day one**.

This guide outlines a research-backed process that covers target segmentation, risk mapping, compliance, and positioning, all while supporting documentation and evidence required for submissions. Whether you're launching an IVD, SaMD, or medical device, RIMR helps you avoid rework, prevent regulatory missteps, and build a product the market (and regulators) wants.

Stepwise Framework: Regulatory-Integrated Market Research (RIMR)

Stage	Description	Objective	Regulatory Tie-in	Deliverables
1	**Opportunity Scoping**	Find unmet needs, define market	Pre-classify device (FDA/IVDR), map regional requirements	Draft intended use, classification map
2	**Voice of Customer (VoC)**	Capture user pain points & workflows	Use as design input per 21 CFR 820.30 / ISO 13485	Requirements doc, feature-risk matrix
3	**Competitive Landscape**	Analyze incumbents, value props	Identify predicates for 510(k) / CE comparison	Predicate map, SWOT with regulatory position
4	**KOL Interviews & Early Feedback**	Validate need, claims, clinical relevance	Feed into usability/HFE and clinical protocols	Advisory board notes, claim refinement
5	**Pricing & Reimbursement**	Assess value vs. cost, payer priorities	Map to CMS codes, HTA pathways, payer evidence needs	Reimbursement brief, payer persona
6	**Risk & Compliance Analysis**	Align roadmap with compliance risks	Map QMS controls, plan for labeling/ad limits	Risk register, early labeling strategy
7	**Messaging & Claim Testing**	Validate claims and communication	OPDP/FTC compliant messaging, promotion rules	Finalized claims, regulatory-safe messaging map

🔗 Tools & Resources (With Official Links)

Tool	Purpose	Link
FDA Classification Database	Product code, regulatory class	FDA Classification
FDA 510(k)/PMA Database	Predicate or PMA comparison	510(k) • PMA
FDA Human Factors Guidance	Usability & human factors design	Download PDF
ISO 13485 Overview	QMS requirements	ISO 13485
CMS Coverage Database	Payer coverage and evidence	CMS Coverage
FTC Advertising for Health Products	Promotional compliance	FTC Health Claims
FDA OPDP	Rules for prescription drug promotion	FDA OPDP

Why RIMR Matters

Skipping regulatory integration during market research leads to **restarts, delays, and denied submissions**. RIMR keeps your entire GTM plan compliant-ready by ensuring that your market data supports regulatory filings, **not just investor decks.**

Biotech Bridge Media

Biotech Bridge Media offers a **comprehensive service package** by integrating business consulting, regulatory, and quality management expertise. In collaboration with **Dr. Srilekha Deka (Script Molecular) and Dr. Jaspreet Seth, QuRA Solutions**, we provide end-to-end solutions, including new product development, regulatory compliance, quality management, and market strategy. Whether you're navigating FDA regulations, implementing ISO standards, or launching a new diagnostic assay, our combined team ensures seamless integration of business, regulatory, and quality frameworks.

Krishnan Allampallam, PhD, MBA, Founder/Owner Biotech Bridge Media,
I started BBM with the goal of helping very busy leaders with ad-hoc small projects they want to do but don't have the resources nor do they have the time to coach a new member. With 25+ years of experience in the biotech industry with a strong technical and business background, I can start on day one running. I can help with the following strategic product management, market research in biotechnology, pharma market space, content development for multi-channel digital marketing branding, product launch planning and execution, sale enablement, sales collaterals, training, technical training

Take a quick look at our Quick Guides Collection https://biotechbridgemedia.com/quick-guides-download

Srileka Deka, MD, PhD, Chief Scientific Officer at Script Molecular, Regulatory Consultant
Srileka, an experienced healthcare executive and a highly skilled scientist with two decades of experience in the biotechnology and molecular device industry. Having worked with small start-ups as well as large companies like Roche, Srilekha has multiple successful submissions to FDA [510(k)] and other regulatory agencies. She led the teams through successful ISO13485 certification and rapid launch of RUO assays. With a rich background of clinical medicine and scientific research, she is enthusiastic about leveraging her knowledge for advancement of diagnostics for improved treatment and disease outcomes in patients.

Jaspreet Seth, PhD. President, QuRA Solutions, QMS Consultant
Jaspreet, a dynamic professional with proven experience (20 yrs) in Quality Systems Regulations, Clinical Research Compliance, College of American Pathologists (CAP) accreditation, Good Clinical Laboratory Practices (GCLP), Quality Assurance, Quality Control, assay and process validations, and customer support experience.

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