

PATRICIA DE COSTA

RESEARCH & DEVELOPMENT | PROJECT MANAGEMENT | INNOVATION

NUTRACEUTICAL | MEDICAL DEVICE | PHARMACEUTICAL | FUNCTIONAL FOOD

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PROFESSIONAL SUMMARY

Visionary R&D leader with over 20 years of experience bridging deep science with commercial strategy across nutraceutical, consumer health, functional food, pharmaceutical, and medical device sectors. Proven track record in shaping innovation portfolios, accelerating product launches, and driving evidence-based claims that strengthen scientific credibility and market differentiation. Experienced in delivering multimillion-dollar innovation pipelines from concept through commercialisation, underpinned by rigorous clinical trials, analytical validation, and regulatory compliance (EU/FDA/EFSA/MDR). Adept at portfolio governance and stakeholder alignment, ensuring innovation investments translate into sustainable business growth. Recognized for coinventing patented technologies, leading clinical research programs, and substantiating health claims through peer-reviewed evidence, I bring both scientific depth and strategic foresight to deliver breakthrough health solutions.

PROFESSIONAL EXPERIENCE

1. INQPHARM GROUP

Director, Head of R&D

July 2010 – Present (Currently in a consulting capacity) | Kuala Lumpur,

Malaysia

Strategic Portfolio & Project Leadership

- Directed a multi-million-ringgit innovation portfolio, balancing risk, resources, and commercial priorities to accelerate time-to-market and maximize business impact.
- Shaped cross-border co-development strategies (EU region), serving as the single point of accountability from concept to commercialization readiness.
- Drove end-to-end innovation execution: feasibility, formulation, packaging, clinical validation, and regulatory submissions (EU/FDA/EFSA) - ensuring products were both compliant and market-ready.

- Scouted and initiated high-value innovation opportunities, leveraging ingredient trends, CMO capabilities, and technology platforms to align with long-term portfolio and growth objectives.
- Led technical and analytical transfers to global CMOs, securing operational readiness, regulatory compliance, and successful international market launches.

<u>Innovation & New Product Development (Ingredients & Finished Products)</u>

- Aligned innovation and commercialisation initiatives with broader organisational strategy and future growth priorities.
- Led a team of over 15 R&D scientists, improving collaboration and efficiency across functions to meet commercial and regulatory goals.
- Managed the full development and launch support of scientifically backed products in consumer health, pet health, and livestock health, covering supplements, functional foods, and oral medical devices in various formats including oral solid dosage, liquid, powder.
- Co-invented two patented ingredients, adding to the company's IP portfolio by overcoming novelty challenges in a crowded market.

Product Validation – Pre-clinical, Clinical & Laboratory Method

- Managed full-spectrum product validation, including pre-clinical, clinical (human and animal), and analytical testing methods, to support market launch, regulatory approval, and CMO readiness.
- Oversaw clinical study design, site monitoring, data reporting, and publication in peer-reviewed journals, strengthening scientific credibility and facilitating smooth regulatory reviews.
- Developed and validated in-house analytical methods to define product specs and ensure successful transfer of methods to external CMOs for manufacturing scaleup.

Regulatory Compliance and Quality Management

- Ensured full regulatory compliance for product approvals, adhering to relevant guidelines/regulations, e.g. EU Medical Device Regulation (EU MDR), FDA, and EFSA requirements.
- Developed comprehensive technical documentation, including EU MDR files, product master files, and regulatory dossiers, to support submissions, internal audits, record-keeping, and end-to-end product lifecycle management.

Commercialisation

- Collaborated with Operations to identify and onboard high-quality, cost-effective CMOs, while securing consistent and reliable sourcing of R&D materials aligned with quality standards and cost targets to support seamless scale-up and timely commercialization.
- Collaborated closely with commercial teams from marketing and business development to support product commercialisation.

2. BIOTROPICS MALAYSIA BHD

Manager, Project Management & Product Development October 2007 – June 2010 | Kuala Lumpur

- Spearheaded herbal-based ingredient development using extraction techniques.
- Developed finished products/health supplements with Malaysian herbal ingredients for international market.
- Established a state-of-the-art research laboratory to enhance R&D efficiency.

3. INNOVAX SDN BHD (DUOPHARMA BIOTECH)

Assistant Manager, Research & Development June 2001 – September 2007 | Kuala Lumpur

- Developed and validated robust analytical methods for a range of generic pharmaceutical products.
- Led multiple bioequivalence (BE) studies within the first two years of my career, collaborating with CROs and key opinion leaders to ensure regulatory compliance and scientific integrity.
- Established a fully functional bioequivalence laboratory from the ground up, significantly enhancing internal research and development capabilities.

SKILLS

- Product Development & Innovation Health/Food Supplements, Substance-based Medical Devices, Pet Supplements, Livestock Products
- Project Management Budgeting, Resource Allocation, Timeline Execution
- Leadership Skills Strong leadership in guiding cross-functional teams and driving performance
- Clinical Research & Regulatory & Quality Compliance GCP, ISO 13485, GMP, HACCP, MDD/MDR, ISO 17025, GMP+
- Intellectual Property & Commercialisation Patent Development, Market Strategy, Sourcing
- Laboratory & Quality Management Analytical Method Development & Validation and knowledge in Quality Systems
- Stakeholder Engagement & Leadership Cross-functional Team Leadership, Business Acumen

KEY ACHIEVEMENTS

- Developed more than 20 scientifically substantiated products across various formats, driving business growth.
- Led the launch of a new animal health R&D division (pets and livestock), including product development and trials, an unfamiliar domain that showcased my adaptability and quick learning.
- Co-invented two patented technologies, showcasing strategic innovation.
- Successfully managed clinical trials valued at over RM5 million, ensuring regulatory compliance and delivering positive outcomes across all studies.
- Co-authored 5 randomized controlled trials in peer-reviewed journals.

• Established and led a bioequivalence laboratory within four years of career progression.

EDUCATION

Master of Science in Instrumental & Analytical Chemistry | University of Malaya, Malaysia 2004-2006

CGPA: 3.87 / 4.00

Bachelor of Science in Applied Chemistry | University of Malaya, Malaysia 1998 – 2001

CGPA: 3.84 / 4.00