David J. Ingamells

Senior Biologics Manufacturing Consultant

Core Competencies

- Upstream/Fermentation
- Cell Line R&D
- Technical Operations
- Biologics Tech Ops
- Lyophilization
- Aseptic Fill/Finish

Products

- Rituxan (Biogen/IDEC), Avastin (Genentech)
- Herceptin (Genentech)
- Aldurazyme (Biomarin)
- Naglazyme (Biomarin)
- Activase (Genentech)
- Zevalin (Biogen/IDEC)
- Dificid (Optimer/Cubist/ Merck)
- Products for: Influenzas, Norovirus, HPV, RSV (Vaxart)

Professional Summary

Mr. Ingamells is a biologics technical operation consultant with over 25 years of experience in industry with a very diverse background in biopharmaceuticals and pharmaceuticals. He is a change agent with proven ability to transform teams, design, construct, commission and has managed manufacturing facilities from process development through commercialization.

He has significant expertise in process manufacturing using mammalian and bacterial cultures at up to a 100,000 liter scale, based upon batch-fed and perfusion technologies. Products include enzymes, viruses and antibodies.

Education

B.S.	Biochemistry	San Francisco State University

Professional Experience

DSI and Ingamells Consulting **2014 - Present**

Biologic Process Consultant

Consulting with biopharma organizations in all aspects of technical operations, including manufacturing, engineering, validation, supply chain, quality and process development.

- Authored and approved the CMC sections of several BLAs, MAAs, CTDs, NDAs and INDs,
- Upstream processing of mammalian cell cultures,
- Characterization of the R&D material, process development and manufacturing,
- Lyophilization process including product preparation, freezing, primary and secondary drying.

Vaxart, Inc. **2015 - 2019**

Vice President, Manufacturing (CMC)

Manage manufacturing, supply chain, production planning, logistics, process development, information technology, facilities, analytical development, quality assurance and quality control.

- Implemented quality systems,
- Identified and contracted new external manufacturers,
- Developed bulk manufacturing process for in-house manufacture,
- Completed and commissioned clinical bulk and tablet manufacturing facility.

Optimer Pharmaceuticals, Inc. **2011 - 2014**

Vice President, Manufacturing

Managed manufacturing, supply chain, production planning, logistics, process development and validation.

- Launched the first commercial product ahead of schedule,
- Managed the development of new formulation and several process changes,
- Implemented the Sales and Operations Planning process.

SAFC Pharma (Sigma-Aldrich) **2006 - 2011**

Vice President, Manufacturing Operations (MMB)

Directed the manufacturing, engineering, validation, metrology, facilities maintenance, purchasing, and materials management departments. Site representative for corporate process improvement.

- Transformed the quality, materials, and manufacturing systems from early clinical stage to commercial readiness,
- Designed, constructed, and commissioned the company's commercial bulk manufacturing and fill/finish facilities,
- Landed key clinical and commercial contracts,
- Successfully produced hundreds of batches for dozens of clients.

BioMarin Pharmaceutical, Inc. **1998 - 2004**

Senior Director, Supply Chain Management & Manufacturing Operations

Managed manufacturing, production planning, materials management, and purchasing. Products included one small molecule, one bacterial-based, and two mammalian-based pharmaceuticals.

- Started and grew the supply chain functions, which included production/capacity planning, purchasing, materials management, and manufacturing,
- Designed, constructed, commissioned, and licensed two bulk manufacturing facilities,
- Drove products through clinical production, process development, and to commercial launch.

IDEC Pharmaceuticals, Inc. (now Biogen Idec, Inc.) **1995 - 1998**

Senior Manager, Manufacturing Operations

Directed purification operations within the commercial facility. Products included two clinical and one commercial mammalian antibodies. Led the group from clinical production through US and EU approval.