Eileen Jacobs

Senior Project Management Consultant

Core Competencies

- Clinical Supply Chain
- New Product Launch
- Parenteral Manufacturing
- Supplier Agreements
- Profolio Management
- GAP Risk Management
- Lifecycle Planning

Products

- Taxotere®
- Lovenox®
- Tygacil®
- Azmacort®
- Nasacort®

Professional Summary

Ms. Jacobs is an experience Project Manager with clinical supply expertise. She is well-versed in project management methodologies, commercial manufacturing, organizational change management, risk management, project planning, team building and open communication. She supports IND, NDA, BLA and MAA submissions and confidently meets acceptance criteria for release of drug products.

Ms. Jacobs spent her 26+ year career dedicated to a relentless mission of helping clients to effectively execute strategy and manage drug development. She oversees complex projects organizing highly skilled and functional teams that shorten timelines and execute project goals.

Education

B.S.	Mechanical Engineering	Drexel University

Professional Experience

Design Space Inpharmatics, LLC **2007 - Present**

Senior Project Management Consultant

- Clinical, API and commercial drug product manufacturing,
- Scale-up, validation, new product launch and clinical supply chain,
- Project planning, execution, and monitoring,
- Identifies issues affecting project timelines by performing GAP analysis,
- Cross-functional team management,
- Communicates project status updates and actions to clients,
- Strong team-building leadership managing client and DSI consultants,
- International project management experience from discovery to launch.

Wyeth Europa Limited **2004 - 2007**

Director – New Product Introductions, TO&PS (Technical Operations & Product Supply) (2007)
Associate Director – New Product Introductions, TO&PS (2005)

- Responsible for continuing development of a planning process involving all stakeholders in the supply of new products, and ensuring agreement of supply strategies for product launches to meet the EMEA (Europe/Middle East/Africa) market needs,
- Managed the successful launch of Tygacil®, within 24 hours of EU license, and Tazocin EF® from a TO&PS NPI perspective for the EMEA region,
- Contributed to the specification of all major new pharma products to achieve well-conceived products, which are efficient to manufacture and meet EMEA market needs,
- Ensured practical plans were created and committed to by all involved parties, for the achievement of each major product launch,
- Managed the setting of launch dates with markets, plants, regional and global stakeholders to ensure aggressive but achievable plans were made,
- Maintained adequate communication with markets regarding changes in registration, pricing and launch date expectations,
- Resolved issues arising between markets and plants where targets become unachievable,
- Contributed to pack design and labelling definition prior to registration to ensure that the commitments made reflected the needs of efficient production and flexible distribution,
- Represented the goals of Regional Commercial Management and Global Business Units in new product planning within the EMEA region,
- Continued to develop the NPI planning procedure and ensure it met the changing environment.

Manager – Technology, TO&PS (2004)

- Controlled and coordinated technical aspects of the manufacture and distribution of existing and new company-owned and licensed products at company sites, third parties and licensees within EMEA,
- Responsible for visiting corporate production sites, third parties and licensees in conjunction with the GCA Group to ensure that production operations were being carried out under conditions that met corporate standards,
- Provided advice and support to European production sites in resolving production issues with established products,
- Participated in the technology transfer processes associated with the on-going manufacturing rationalization process, including project management and team coordination,
- Provided technical information to manufacturing sites to assist in new or transferred product start-up, and to advise and assist in the introduction of these into routine production,
- Responsible for ensuring that initial production batches at new locations were manufactured and tested according to corporate standards in conjunction with the QA Group,
- Worked with third parties, licensees and corporate sites to standardise packaging and formulations with a view to future consolidation of production operations at the European manufacturing sites,
- Coordinated new product start-up activities in the European plants and third parties,
- Assisted manufacturing affiliates with technical, quality and regulatory issues.

Eximias Pharmaceutical **2001 - 2003**

Manager – Pharmaceutics

- Managed process transfers for current and new products and ensured the successful startup of final dosage form manufacturing and packaging in a timely manner,
- Ensured process compliance and managed process scale-up and validation, as well as the manufacture of materials for clinical supplies,
- Managed all process development activities as required to transfer and manufacture product in accordance with all regulatory guidelines and mandates in the US and Europe,
- Assisted in the management of active pharmaceutical ingredient (API) manufacturing, as required to ensure adherence to cGMP's,
- Managed technology transfer of current product to a suitable qualified manufacturing facility,
- Liaison between company and manufacturing contractors on all process and product related issues,
- Managed cost of goods related issues, reduced COG's wherever possible in keeping with overall company strategy,
- Responsible for packaging & labeling of all clinical supplies in US, Europe & ROW,
- Developed tracking system for verification of shipment of all clinical supplies,
- Established documentation filing control system for batch records and development reports, including a consistent and efficient documentation system for regulatory filings,
- Established and managed manufacturing schedules and ensured expeditious timing of all product lots in keeping clinical and commercial release requirements,
- Assisted on technical aspects of annual QA audits of manufacturing contractors,
- Managed all CMC documentation input to regulatory affairs for IND, NDA, CTX and MAA filings.

Glaxo Smith Kline **2000 - 2001**

Manufacturing Engineer – Pharmaceutical Technology–Parenterals

- Supervised and co-ordinated the daily activities of the team and areas supporting the manufacture of first time quality parenteral products to support development and clinical needs,
- Performed secondary biopharmaceutical manufacturing of mAb's for clinical studies,
- Prepared master batch records, process documentation, product summary reports, and bulk production records,
- Evaluated, recommended, and provided documentation for the procurement of new equipment,
- Participated in mock GMP internal audits,
- Review of cleaning, preparation and sterilization of equipment,
- Compounding of bulk solutions, including optimization, performing calculations, ensuring general chemistry and safety principles are followed,
- Preparation of filtration/filling kit,
- Utilizing aseptic technique during filtration, filler set-up and manufacturing,
- Responsible for installation and operational start-up of pharmaceutical processing equipment,
- Assisted in technology transfer of processes to WSO and clinical contract manufacturing sites,
- Performed review of clinical manufacturing documentation to ensure compliance with cGMPs, SOPs, and company standards.

Rhone-Poulenc Rorer Pharmaceuticals R&D **1994 - 1999**

Research Process Engineer – Clinical Manufacturing – Parenterals

- Supported operations of a sterile research and manufacturing facility with strict regard to cGMP compliance and safety regulations,
- Managed a grant-in-aid phase IV project through a contract manufacturer,
- Manufacture toxicological and clinical supplies according to cGLP's and cGMP's both internally and through contract manufacturers,
- Responsible for water for injection (WFI) system including operation and sampling,
- Evaluatee, recommended, and provided documentation for the procurement of new equipment,
- Responsible for installation and operational start-up of pharmaceutical processing equipment,
- Supported equipment and facility validation activities within the GMP sterile manufacturing areas that includes writing and executing qualification protocols for utilities and processing equipment,
- Supported the development of a cleaning verification program.

Research Process Engineer - Clinical Manufacturing - Aerosols/Solids/Liquids (1995)

- Involved in pre-approval inspection to support commercial product launch,
- Responsible for purified water system including operation, sampling, and validation,
- Supported development, product scale-up, and production scale manufacture of IND and NDA programs in clinical manufacturing,
- Supported operations of a non-sterile research and manufacturing facility with strict regard to cGMP compliance and safety regulations,
- Prepared and revised relevant facility and equipment standard operating procedures,
- Responsible for installation and operational start-up of pharmaceutical processing equipment,
- Supported all equipment and facility validation activities within the GMP non-sterile manufacturing areas, including writing and executing qualification protocols for utilities and processing equipment,
- Operated and maintained equipment used in granulating, drying, tableting, encapsulating, coating, and aerosol filling,
- Evaluated, recommended, and provided documentation for the procurement of new equipment,
- Coordinated a calibration and maintenance program to insure that GMP equipment is in suitable condition for use at all times,
- Supported the development of a cleaning verification program.