Christopher J. Brookes, Ph.D.

Senior Drug Substance Consultant

Core Competencies

- API Manufacturing
- Process Optimization
- Plant & Site Utilization
- Authoring Submissions
- Tech Transfer
- Generic Products
- QA/Compliance
- Pilot Plant Operations

Professional Summary

Dr. Brookes has 40 years of diverse management and business experience in API, fine chemical manufacturing, and contract custom synthesis. Principle responsibilities have included operations and project management, product introduction, product costing, regulatory compliance, and the achievement of financial and strategic targets. Product introduction ran the gamut from process development chemistry through large scale manufacturing. His hands-on and analytical approach has led to the successful commercialization of several API's, chemical process optimization, and improved site operations, including plant utilization.

- CMC NDA submission including authoring, QA checking and editing of drug substance and drug product module 3 CMC sections,
- Directed the cGMP manufacture of bulk API's and developed SOPs, batch records, policies and technology transfer documentation,
- Directed the activities of a 17 reactor cGMP pilot plant (30 to 750 gallon scale), four kilo labs.

Prior to joining DSI, Dr. Brookes served has as Technical and Operations Director for three bulk API manufacturing facilities. He holds a Ph.D. in Chemistry from the University of Birmingham.

Education

Ph.D.	Chemistry	University of Birmingham
B.S.	Chemistry	University of Birmingham

Professional Experience

Design Space InPharmatics, LLC **2019 - Present**

Senior Drug Substance Consultant

Provide consultant services in the area of API and drug substance manufacturing.

- CMO site selection,
- In Plant monitor of API production,
- Review and Author CMC sections of submissions.

Johnson Matthey **2008 - 2013**

Process Optimization Leader

- Review API chemistry to determine yield and process optimization opportunities,
- Advise on make versus buy decisions for key API raw materials, and seeking lower raw material costs,
- Worked on the development of more efficient manufacturing processes across the division's three bulk API manufacturing sites,
- Assisted with technology transfers and resolution of operational and scale-up issues,
- Directed the cGMP manufacture of bulk API's for the U.S. high potency generic market. Managed four direct reports and 90 indirect covering production, process and project engineering, maintenance, EHS, and logistics,
- Responsible for site annual operating and capital budgets,
- Increased production output by 50% over two years by changing the site's operational philosophy,
- Rationalized capital investment by the development of a site master plan,
- Led the operational group of the two sites of the division's contract services business for six months during a transition period.

Cambrex **2006 - 2007**

Site Director

Responsible for a 22 employee site operation. Provided leadership and direction to commercial production and custom development projects involving high potency compounds, process and analytical development, QC, QA, facilities, and environmental, health and safety. Developed proposals for custom development projects.

- Improved site financial performance by equipment change-out and facility upgrades,
- Instituted a quality systems improvement plan.

Noramco, Inc **2005 - 2005**

Manager, Process Validation (Contractor)

- Managed process and cleaning validation programs for the manufacture of API's,
- Led technology transfer and scale-up of API's.

Rhodia Pharma Solutions **2004 - 2004**

Director, Operations

Directed the activities of a 17 reactor cGMP pilot plant (30 to 750 gallon scale), four kilo labs, and EHS, maintenance, and materials management functions. Managed 6 direct reports and 24 indirect.

- Organized the hiring of the management team, operators, mechanics, and support personnel,
- Led the start-up of an idle process research and development facility,
- Prepared and reviewed SOP's for the facility,
- Managed the commissioning and qualification of process equipment and facilities,
- Led the commissioning of hydrogenation, low temperature reactor, and dryer systems.

Rhodia Chirex **2001-2003**

Pilot Plant Manager

- Transferred in and directly supervised the running of custom synthesis projects in the pilot plant,
- Improved cGMP status of the pilot plant operation to support customers' pre-clinical and early phase clinical,
- Reviewed all procedures prior to scale-up. Conducted operator training and process hazards review,
- Prepared qualification protocols for reactor systems, and for isolation and drying equipment,
- Prepared and managed the pilot plant schedule. Maximized pilot plant usage.

D.H. Gold Associates, Inc.

2000 - 2000

Consultant

- Performed project work for client pharmaceutical outsourcing company including the preparation of process validation protocols and analytical method manuals.

Novartis Pharmaceuticals Corporation **1985 - 1999**

Director, Chemical Production and Solid Dosage Forms

Directed the cGMP production of bulk API's and solid dosage forms at several facilities. Managed the activities of production, maintenance, and laboratory groups consisting of 80 employees engaged in the manufacture of 20 API's and intermediates, and 20 drug product families for captive use and sales. Developed annual operating and capital budgets, standard costs, and production programs.

- Increased plant utilization by introducing the in-house manufacture of a product that contributed $10 MM in savings over three years,
- Led process improvement/control and monitoring initiatives over ten years resulting in yield and cycle time improvements for several products,
- Successfully expedited the introduction of a new product requiring a $3.5 MM investment resulting in $30 MM drug product sales in the first six months,
- Prepared and reviewed manufacturing procedures, validation reports, DMF's, and NDA supplements. Sustained track record of timely NDA approvals over ten years contributing $3 MM in profits,
- Managed operations to maintain compliance with FDA, safety, and environmental regulations. Directly involved with FDA on compliance inspections, PAI's, and supplement reviews,
- Organized integration of the bulk pharmaceutical plants including all outsourcing activities. Participated in domestic and overseas audits of third party API manufacturers,
- Served as primary liaison with parent company on all matters pertaining to worldwide chemical manufacturing.