

BioProcess Technology Consultants and L&K Biosciences

*Combining strategic business, technical, and regulatory services to
ensure successful product development worldwide*



Our Mission

*To enhance the overall value of client
companies through the design and
implementation of effective biopharmaceutical
development and commercialization programs
and strategies to enable delivery of key
business milestones*

*To reduce the risks associated with
biopharmaceutical manufacturing activities*

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BioProcess Technology Consultants/L&K Biosciences Strategic Alliance

- Provide clients worldwide with access to BioProcess Technology Consultants and L&K Biosciences by
 - Increasing depth and breadth of resources available to both company's clients
 - Leveraging BioProcess Technology Consultants' biomanufacturing supply and demand databases and L&K Bioscience's Process Guide
- Expand existing project management tools to better manage and monitor all CMC activities, ensuring
 - Seamless oversight of development and manufacturing programs worldwide
 - Comprehensive product discovery and development support throughout the product lifecycle

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BioProcess Technology Consultants

- Founded in 1994
- Headquarters in the metropolitan Boston, MA area
- Twelve full time employees supported by over 20 additional specialized subcontractors
- A team of accomplished professionals with significant biopharmaceutical industry experience
 - Experience from product discovery through commercialization
 - Founders and early employees of several successful start-up biotechnology companies
 - Executives from large biotechnology and pharmaceutical companies

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L&K Biosciences

- Founded by Lars Skriver and Kim Hejnaes in 1998
 - Over 30 years combined experience at Novo Nordisk
 - Founders of SMC Biotech
- Experts in process development and scale-up, outsourcing, technology transfer, strategic operations and management
- Experience working within a CMO and as customers of contract organizations
- Headquarters in Copenhagen, Denmark
- Provided consulting services to over 45 companies

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BioProcess Technology Consultants Track Record

- Provided consulting services to over 300 companies worldwide, including
 - Large multi-national pharmaceutical companies
 - Small and mid-size biopharmaceutical companies
 - Start-up (virtual) companies
- Supported clients through minor and major process changes, both technically and in design of suitable comparability programs
- Managed several product development programs from initial cell line generation through packaging, labeling, and distribution
- Contributed to regulatory filings for products in all stages of development and commercialization

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BioProcess Technology Consultants and L&K: Providing Expert Consulting Services Worldwide

- Proven success in meeting project goals and corporate milestones
- Experience with a wide range of products (hormones antibodies, fusion proteins, vaccines)
- Knowledge and experience with several biopharmaceutical expression systems
 - Microbial (*E. coli*, yeasts, pseudomonas, other)
 - Mammalian (CHO, NS0, BHK)
 - Natural sources (plants, animal, reptile)
 - Transgenic expression systems (avian, animal, plant)
- Experts in all aspects of biopharmaceutical CMC activities
 - Obtaining bulk drug through vialled product
 - De-risk client CMC programs to achieve earlier introduction to the clinic

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Our Team

- **Howard L. Levine, Ph.D.**
 - Founder of BPTC, Expert in process development, manufacturing operations, and regulatory strategy, former Vice President, Operations
 - Formerly Genentech, Amgen, Xoma, Repligen
- **Thomas C. Ransohoff, M.S.**
 - Expert in GMP manufacturing and process technology development, former VP Program Management and Product Development
 - Formerly TransXenogen, Dyax, Repligen, Xoma
- **Susan Dana Jones, Ph.D.**
 - Outsourcing, program management, and expression system expertise, co-founder two successful biotech companies, former VP Technology and Strategy
 - Formerly Serenex, Dyax, Avant, Dana Farber Cancer Institute
- **James Blackwell, Ph.D., M.B.A.**
 - Cell culture development, regulatory filings, and due diligence expertise, former Sr. Manager, Technical Operations; Process Engineer
 - Formerly Abbott, Repligen, Genzyme
- **Patricia Seymour, M.B.A.**
 - Expertise in outsourcing, supply chain management, and business strategy, former Sr. Director of Supply Operations and former sales director for several CMOs
 - Formerly Millennium, Covance, Collaborative, Immunogen

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Our Team

- **Sheila Magil, Ph.D.**
 - Protein chemist with extensive analytical and formulation experience, former Sr. Manager, QC; VP Process Development
 - Formerly Biomeasure, Bion, Alkermes,
- **Alex Kanarek, Ph.D.**
 - Expertise in regulatory compliance, technology transfer, and product development, former Director Product Development and New Business for vaccine companies
 - Formerly Connaught Laboratories Canada, Welcome Laboratories
- **Frank Castillo, Ph.D.**
 - Expertise in expression systems, gene therapy product development, and GMP operations, former Scientific Director, Fermentation and Cell Culture Development
 - Formerly Berlex (subsidiary of Schering), Xoma, Engenics
- **Rick Stock, Ph.D.**
 - Fermentation expertise and specialist in computer modeling of biomanufacturing processes, former Assistant Director, Bioprocessing Pilot Laboratory
 - Formerly BioPharm Services, Worcester Polytechnic Institute
- **Dawn Ecker, M.S.**
 - Specialist in molecular biology, database management and analysis, former laboratory manager
 - Formerly BioPharm Services, Amherst

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Our Team

- **Lars Skriver, Ph.D.**
 - Expert in manufacturing strategies, analytical development, outsourcing and due diligence, former Operational Manager in Protein Technology and Process Development
 - Formerly Novo-Nordisk, co-founder of L&K Biosciences
- **Kim Hejnaes, Ph.D.**
 - Expert in project management, process design, scale-up, GMP manufacturing and process validation, former Director Project Management
 - Formerly Novo-Nordisk, co-founder of L&K Biosciences

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Our Services

We facilitate the operational, technical, and regulatory elements of drug development to meet the specific requirements of our clients and to reduce time to market



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Business Planning and Strategy

- Integrate manufacturing approach into overall company strategy
 - Risk analysis and management
 - Enable product partnering
 - Options to meet market projections
- Evaluate business opportunities
 - Product in-licensing or acquisitions
 - Strategic or VC investment
 - Co-development options
- Conduct technical due diligence
 - Assessment of product development history
 - Feasibility of manufacturing approach
 - GAP analysis

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Process Development

- Evaluate strategic options for new or continued product development
- Development of manufacturing processes
 - Selection of optimal expression system
 - Cell culture and fermentation
 - Recovery and downstream processing
- Design and review of analytical methods
 - Product characterization
 - Comparability testing to support process changes
- Formulation development
- Implementation of Process Analytical Technologies (PAT) and Quality by Design (QbD) at development stage

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BioProcess Guide™

- The BioProcess Guide™ is a knowledge tool designed to help companies save time in bringing biopharmaceutical products to market by providing full descriptions, reviews and, references for all development activities.
 - An abbreviated free version containing summaries of all biopharmaceutical development activities is available on-line
 - The full version is available to registered customers of BPTC and L&K

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Regulatory and Quality

- CMC Regulatory Support from Pre-clinical through marketing authorization
 - Organization and preparation of submissions (including electronic submissions)
 - Attendance at meetings with regulatory agencies
- Establishment and assessment of Quality Systems
 - Documentation preparation and review
 - GMP training and compliance audits
 - Pre-approval inspection audits
- Quality Control
 - Setting of product specifications
 - Design of stability programs
- Validation
 - Master planning; protocol preparation and review

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Manufacturing Strategies

- Develop Drug Substance manufacturing strategies
 - Evaluate outsource, build, acquire, or renovate options
 - Facility review and conceptual design
 - Capacity planning
- Identify, qualify, and recommend Contract Manufacturing Organizations (CMOs)
 - Match client requirements with suitable CMO options
 - BPTC and L&K act independently of any CMO
- Drug Product manufacturing
 - Evaluate container/closure systems
 - Product presentation
 - Labeling, packaging and distribution

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Manufacturing Capacity Database

- Separate supply and demand databases
 - Supply database includes company, location, manufacturing technology, number and scale of bioreactors, status and date online
- Applications of the databases
 - Projecting supply and demand
 - Assessing demand for industry products and services
 - Resource to support CMO selection
 - Market penetration or market opportunity for a given indication or indication class
 - Facility lifecycle management

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Manufacturing Operations

- Management of Drug Substance and Drug Product manufacturing
- Optimization of manufacturing operations
 - Time-to-market and profitability analysis
 - Cost of Goods modeling
 - Improve efficiency and implement cost reduction strategies
 - Troubleshoot production issues
 - Non-conformance resolution
- Person-in-plant services
 - Oversee manufacturing operations
 - Provide on-site supervision and deviation resolution

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Program Management

- Manage day to day CMC activities
- Timeline planning and management
- Budget predictions, analysis, and tracking
- Management of Outside Service Providers, including
 - Cell line production and testing, Drug Substance and Drug Product manufacturing, analytical and release testing, product storage and distribution
 - Vendor selection and negotiation of development, supply and quality agreements
 - Oversight of technology transfer
- Project communications and oversight

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Project Management Tools

- Built on solid technical knowledge within multiple fields
 - Cell line development and cell banking,
 - Upstream and downstream process development
 - Analytical development and quality control
 - Formulation development and stability testing
 - Scale up and production under cGMP
- Combines in depth understanding of duration, linkage, and termination criteria of the activities mentioned
- Includes documentation index to facilitate project tracking and electronic regulatory submissions

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Our Advantage

- Client-tailored advice and assistance to deliver comprehensive product discovery and development support from initial concept to commercialization
- Unique expertise in technical, business, operational, and regulatory areas spanning all phases of product lifecycle
- **Our proven track record in product development, process optimization, scale-up, manufacturing, quality, regulatory, and commercialization help ensure our client's success**

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Contact Us



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