An Introduction to Double Dragon Consulting

www.doubledragonconsulting.com

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About DDC

- Our Experience:
  - All dosage forms, aseptic processes, API manufacture, OTC
  - Remediation of 483 observations, Warning Letters, Consent Decrees
  - Supplier qualification (assessments, audits)
  - 3rd party batch review / data integrity review / retrospective reviews
  - Construction, commissioning, and maintenance of aseptic processing facilities
  - International (US, EU, Asia)
- Our Offices
  - Headquarters in North Carolina
  - Representative Office in Shanghai, PRC
- Our Associates
  - Global network of experienced independent consultants

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About DDC

- Our Mission
  - To respect cultural differences in our efforts to positively CHANGE non-compliant behavior
  - To deliver sustainable solutions through discussion, mentoring, and coaching
  - To find and implement a “critical path” plan to help client achieve compliance
  - To utilize an optimal mix of in-country and international experts as well as Internet technology to achieve compliance and manage costs
  - To provide US and in-country senior industry experts with a proven track record of successful Health Authority interaction

Representative Client List

- Novartis Vaccines (US, EU, China)
- Novartis Pharma
- Novartis Consumer Health
- GSK
- Schering Plough
- Sandoz (EU)
- Genentech
- Hospira
- Apotex (Canada, India)
- Forest Research Institute
- MedImmune
- Sanofi Pasteur
- Merck
- Cardinal Health
- Bayer
- Hoffmann LaRoche
- Steifel
- NuPathe
- Cook Pharmica
- Washington Homeopathic Products
- Teva
- ClinAudits
- Marianna
- Vertellus
- CibaVision
- Novacyl (China, Thailand)
- Dynavax
- URL Mutual
- Canada Testing Lab

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DDC Principal

STEPHEN SHENG is the Head of Asia Operations of Double Dragon Consulting (DDC), Inc., a consulting firm with a network of Subject Matter Experts (SMEs) located in USA, Europe, and Asia Pacific. Mr. Sheng has a Master degree in Quality Assurance and with over 29 years of industry (drug, device, vaccine, biotech, dietary supplement) experience in quality management and regulatory compliance. Prior to become a consultant, Mr. Sheng has held various management positions at pharmaceutical and medical device companies and was responsible for product release, customer complaints and adverse events, investigations and CAPAs, internal audits, supplier qualifications, regulatory agency inspections, training, etc.

Mr. Sheng has conducted numerous GMP and ISO audits for pharmaceutical, biotech, medical device, API, and chemical companies. Mr. Sheng is active in many professional organizations and is currently the Editorial Board Member of the ASQ Professional Journal on Software Quality. Mr. Sheng is a frequent guest speaker at various conferences and meetings and has published several articles on quality-related topics.

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DDC Principal

DR. GEORGE BERNSTEIN is the Principal of Double Dragon Consulting, Inc., a consulting firm with a network of Subject Matter Experts (SMEs) located in USA, Europe, and Asia Pacific (China, India). Dr. Bernstein has a Ph.D. in Chemical Engineering with more than 30 years of experience in pharmaceutical manufacturing and compliance. Since 1988, Dr. Bernstein has consulted with, and held positions of increasing responsibility with major pharmaceutical companies. He has lectured on quality systems and root cause analysis to industry trade groups, quality organizations, and at Interphex, and has consulted nationally and internationally.

Dr. Bernstein's experience, insights, and innovative problem solving have been integral to his work which ranges from GMP compliance, facility design, construction, and commissioning to business process re-engineering and process optimization. He has developed global quality standards (GLP, GCP, GPP) for a major international pharmaceutical company, and has assisted many clients with remediation activities and communications with the US FDA.

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Our Expertise

- Culture change strategies for compliant behavior
- Integration / change management for M&A
- Inspection readiness
- Gap assessments
- Data Integrity Audits of electronic and manual systems
- Remediation planning and execution
- Training, coaching / mentoring
- Preparation of official Health Authority (FDA/MHRA/EMA/etc.) communications, including responses to FDA 483 observations, Warning Letters, monthly update reporting
- 3rd party batch review
- Supplier qualification

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DDC Service Offerings

- Quality and Validation support
- Training
- Regulatory
- Engineering
- Project Management
- Technical – analytical method development

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DDC Capabilities

- Quality and Validation Support
  - Lead all aspects of compliance remediation activities
  - Conduct deviation / product or lab failure investigations
  - Evaluate / develop procedures, processes, and documentation to meet US and EU requirements
  - Prepare Validation Master Plan
  - Prepare / evaluate / execute validation protocols (process, equipment, cleaning, analytical methods, etc.)
  - Third Party independent review of deviation, change control, and
  - validation reports
  - Evaluate change control, deviation, and validation reports
  - Conduct audits (including mock PAI) / compliance gap assessments
  - Health Authority inspection readiness, including managing “war room” during inspections

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DDC Capabilities

- Training
  - Aseptic Operations including Gowning Qualification
  - Deviation Management, Root Cause Analysis, CAPAs
  - Internal Audits
  - GMP regulations (US, EU, China)
  - Technical Writing
  - Conduct during an FDA inspection

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DDC Capabilities

- Regulatory
  - Prepare / review regulatory (IND, NDA, ANDA) submissions
  - Prepare / review CMC sections of regulatory submissions
  - Perform risk assessment and crisis management
  - Establish PAI action plan and execute remediation activities

DDC Capabilities

- Engineering
  - Prepare conceptual designs / review designs for pharmaceutical manufacturing facilities, to include personnel and materials flows, facility layouts and manufacturing processes, HVAC system, utilities, automation system
  - Provide expert guidance on class A/B cleanroom and aseptic design (RABS or isolator design) to meet US, EU, and China requirements
  - Provide guidance on equipment qualification and commissioning
  - Establish routine / preventive maintenance programs

DDC Capabilities

- Project Management
  - Develop Project Plan with milestones, timelines and resources
  - Establish and run a project management office (PMO)
  - Establish / maintain work stream status reporting and tracking system
- Marketing
  - Provide guidance or assist in product launch in US
  - Identify qualified contract manufacturer in China
  - Search for in-license/out-license opportunities in China

Contact Information

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