An Introduction to Double Dragon Consulting

www.DoubleDragonConsulting.com

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DoubleDragon 双龙咨询 Consulting

About DDC

Our **Experience**:

- All dosage forms, aseptic processes, OTC
- Remediation of 483 observations, warning letters, consent decrees
- All phases of operation from 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

Clients

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

DDC Principal

Stephen Sheng, MSQA

- Principal Double Dragon Consulting
- MS Quality Assurance, BS Biochemistry
- ASQ Certified Quality Auditor and Certified Quality Engineer
- 24+ years of Pharma experience
- Wide Range of experience:
  - OSD, Injectables, Vaccines, Medical Devices, APIs, and Dietary Supplements
  - 483, Warning Letter, and Consent Decree Remediation
  - Investigations and CAPAs
  - Aseptic Operator Training
  - Supply Chain and Supplier Qualification
  - Customer complaints
  - Annual Product Reviews
  - Audits for ISO 13485 , MDD, and CE Marking
  - Project Management

DDC Principal

George S. Bernstein, Ph.D.

- Principal Double Dragon Consulting
- Ph.D. in Chemical Engineering
- 25+ years of Pharma experience
- Wide range of experience:
  - Quality Systems Development, Remediation, FDA communications
  - GMP, GCP, GLP, GPP Quality Guidelines
  - Operational Excellence
  - Training
  - Project/Program Management
  - Facility Construction and Commissioning
  - Investigations / Root Cause Analysis
  - Business Process Re-engineering

Our Philosophy

Experienced Professionals

- We provide consultants with the right expertise and experience from our global network to meet your needs – subject to your review and approval

Flexibility:

- Work can be performed on site or remotely via Internet

Sustainability

- Our goal is to transfer our knowledge to your company so that together we achieve a sustainable solution

DDC Capabilities

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

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 / compliance gap assessments

DDC Capabilities

Training

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

DDC Capabilities

Regulatory

- Prepare / review regulatory (IND, NDA, ANDA) submissions
- Prepare / review CMC sections of regulatory submissions
- Perform risk assessment and crisis management
- Perform mock Pre-Approval Inspection (PAI)
- 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 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 China
- Identify qualified contract manufacturer in China
- Search for in-license/out-license opportunities in China

Projects Experience – 1

Novartis Vaccines & Diagnostics

- Location: China
- Year: 2010-2011
- Work Scope: Aseptic Operations, Supply Chain, Technical Transfer, and Engineering projects (bulk, fill/finish, QC).
- Deliverables/Outputs:
  - Successfully led remediation projects for bulk, fill/finish, packaging, warehouse, and QC Lab areas including construction, equipment selection and procurement, commissioning and qualification, and process validation.
  - Established training materials and provided training to hundred of employees on aseptic processing and techniques including gowning qualification and environmental monitoring.
  - Recommended the selection of aseptic filling lines and critical equipment. Completed installation, commissioning, qualification and validation, which covers syringe filler, vial filler, aseptic filling suite, QC sampling suite, packaging area, & critical utility systems.
  - Successfully supported the daily functions within Engineering and Supply Chain departments.

Projects Experience – 2

Training Projects (Merck, Sanofi, Sandoz)

- Location: US, EU
- Year: 2010-2011
- Work Scope: Aseptic Operations, formulation, bulk, fill/finish, QC, warehouse).
- Deliverables/Outputs:
  - Led project to evaluate compliance risk and to recommend improvements to training organization, training processes, and training effectiveness.
  - Led effort to evaluate/develop training materials for Operations, Deviation Management, and shop floor Quality Assurance departments.
  - Acting as interim head of training for parenterals company to ensure training compliance and to improve the effectiveness of training materials.

Projects Experience – 3

Compliance/Remediation Projects (Hospira, Sandoz, WHP, CibaVision)

- Location: US, EU
- Year: 2010-2011
- Work Scope: Aseptic Operations, QA, Deviations Management.
- Deliverables/Outputs:
  - Acted as 3rd party reviewer of parenteral manufacturer's deviation investigations, performed as a part of company's warning letter remediation. Role included coaching and mentoring.
  - Led QC lab compliance remediation effort for a medical device manufacturer. Project included QC audits and project plan development.
  - Led warning letter remediation project for small OTC manufacturer. Project involved training, documentation redesign, cleaning validation studies and direct interaction with the company owners and FDA.
  - Prepared response letter and periodic updates to US FDA following receipt of 483 observations.

Projects Experience – 4

Novartis Vaccines & Diagnostics

- Location: EU
- Year: 2009-2010
- Work Scope: Deviations Management and Training
- Deliverables/Outputs:
  - Reviewed hundred of deviation reports for adequacy, completeness, and GMP compliance.
  - Developed and implemented qualification and mentoring programs for investigators and QA reviewers.
  - Mentored and qualified 50+ investigators and QA reviewers.
  - Established training materials and provided training to hundred of employees on investigations, root cause analysis, and CAPAs.
  - Company successfully passed 2 FDA inspections.

Projects Experience – 5

Sanofi Pasteur

- Location: US
- Year: 2008
- Work Scope: Aseptic Operations (validation, bulk, fill/finish, QC).
- Deliverables/Outputs:
  - Validation of vaccine facility – developed Basis of Design documentation for sterile syringe filling facility that utilized high speed syringe filler with Restricted Access Barrier System (RABS) or Isolator technology.
  - Developed process flow diagrams for new manufacturing processes which were used to evaluate process robustness and SOPs.
  - Developed sample coordination process to ensure that all samples collected for cleaning, process, and equipment validation were accounted for.

Projects Experience – 6

GSK

- Location: Puerto Rico
- Year: 2005-2007
- Work Scope: Consent Decree (CD) Project.
- Deliverables/Outputs:
  - Performed third party certification of all manufacturing deviations, OOS investigations, and customer complaints.
  - Reviewed and certified 1000+ investigation reports for adequacy and GMP compliance.
  - Established and implemented a tracking system for all deviations reviewed.
  - Provided quarterly updates to FDA.
  - Mentored all investigators and QA reviewers.
  - Company successfully passed FDA inspection and released from CD.

Projects Experience – 7

Schering Plough

- Location: Puerto Rico
- Year: 2002-2004
- Work Scope: Consent Decree Project.
- Deliverables/Outputs:
  - Successfully led a team to investigate and close 100+ manufacturing deviations.
  - Successfully led Deviation Management System remediation projects including the re-design of the TrackWise® system.
  - Performed in-depth organizational assessment of entire site's ability to manage deviations (investigations and CAPAs).
  - Established training materials and provided technical writing training to hundreds of employees.

(Company successfully passed FDA inspection and released from CD.)

Summary

Efficiency

- We employ a Right First Time approach
- We will delivery your project on time and within budget

Quality

- We will focus on knowledge transfer to your people
- Together, we will build a sustainable Quality System

Compliance

- We have the knowledge of US, EU and China GMP requirements
- We have the technical expertise in all dosage forms
- We will help you get there and stay there

LET US PUT OUR TEAM TO WORK FOR YOU

Contact Information

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