Shadle Consulting Services
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Shadle Consulting Services welcomes new Associates in 2008

Shadle Consulting Services, a San Francisco Bay Area based firm, extended its breadth and depth of consulting services during 2008 by adding new consultants in the areas of:

- Quality by Design
- Quality Assurance/Control
- Regulatory Compliance

We are proud of our successes in 2007-2008, which helped our clients to successfully accomplish their key objectives, including:

- FDA approval of a bio-analytical methods comparability protocol to determine product potency
- Successful technology transfer for both a primary biopharmaceutical manufacturing process, the aseptic filling operations, and QC in-process and release testing to a new site overseas
- Technical, compliance, and Quality Systems auditing, remedial advice and strategy for the primary and secondary manufacturing of multi-classes of pharmaceutical and biological products
- Developed corrective action/preventative action strategies which aided in the preparation of FD-483 response letters
- GMP Training, delivered on-site and via external organizations (University of Wisconsin; Ohlone College)
- Invited lecture at DMPQ, FDA (D. Lobato)

Our Associates now include the following:

Madelyn Marino, RAC
Daniel Lobato, B. Sc.
Gillian Edwards, B.Sc., M.S., RSM
Doris Conrad, B.Sc.
Robert Hageman, Ph.D.
Paula Shadle, Ph.D.

We have many years of solid, hands-on pharmaceutical experience with drugs, biopharmaceuticals, and vaccines, from our work in a variety of positions including:

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- QC: bench level through VP level; QC methods validation
- QA: Establishing quality systems, site GMP compliance programs, product release functions, auditing, SOP preparation, Change Control, Deviation/Failure investigations and CAPA reports; product annual review procedures, records review,
- RA: Preparation of BLA/PLA CMC sections, comparability protocols, annual reports, and Drug Master Files for drugs, vaccines, stem cell products, and biopharmaceuticals
- Process development: Biopharmaceuticals, chromatography, process validation, and defining design space
- Analytical development: State of the art methodology for the analysis of raw materials, APIs, and final products including methods validations
- More

Contact us with your needs! For more information, visit our website at www.biopharmpro.com