Mission

The Management and staff of SEAS, Inc. are committed to providing a level of service which exceeds the expectations of all with whom we work.

To that extent, we shall:

Continuously employ a "DO IT RIGHT THE FIRST TIME" approach

Maintain service quality surpassing customer expectations

Dynamically promote total cross-functional process ownership

Strive for ongoing process improvement increasing ROI

Openly and honestly communicate and support all Stakeholders

Promptly and proactively respond to questions or issues

TO:

SEAS Inc.
San Diego, California
USA

SEAS Inc.

A partner of Pharmaceutical Manufacturer

We Develop and Implement a Roadmap to Supplier Certification by:

Determining which US FDA Guidance/Compliance is necessary for a "Contractor Manufacturer" in following activities:

1. Formulation
2. Fill and finish
3. Chemical synthesis
4. Cell culture and fermentation, including biological products
5. Analytical testing and other laboratory services
6. Packaging and labeling

Guide the Pharmaceutical Contract Manufacturer in developing a formal and agreed upon "Quality Agreement" in following areas:

1. Quality Responsibilities
2. Facilities and Equipment
3. Material Management
4. Product Specific Terms
5. Laboratory Controls
6. Document Controls
7. Change Control

"When it comes to finding your way through the regulated product development maze, most people get lost and eventually just give up, not Charlie. He is very good at defining the shortest route with the highest quality through the maze if you listen to him and follow his guidance."

Greg Gulden, VP Device Engineering, Baxter Hospital Products

A good place to start is:
Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.
Quality Risk Management
Pharmaceutical Quality Systems

What You Need…

The US FDA expects parties engaged in contract manufacturing operations to implement quality management practices. While the Owner is ultimately responsible for product the Contracted Facility must comply with CGMP regulations that apply to the operations in which that Contracted Facility is engaged.

Key Offerings

We can do all of this given the time and support. The documentation for compliance is basically the same for both Pharma and Device.

Key Clients

- Hospira
- Zimmer-Biomet
- Fresenius Medical Care
- Johnson and Johnson
- Baxter Hospital Products

Contact Us

Charlie Gragg
Software Engineering Applications Solutions
Email: chgragg@seas-inc.us
Office: 760.666.2914
Cell: 760.470.2419
www.seas-inc.us/