

Sound Advice + Superb Execution

https://www.suvedallc.com/

SUVEDA SOLUTIONS LLC- ABOUT US

- Limited Liability Corporation registered in California, founded in 2012
- Consulting in the areas of Biotechnology and Software Development
- Shalaka Purohit- Biotechnology
 - 27 years of Industry Experience
 - 15 years employment in progressively senior roles
 - 12 years in Consulting
 - Consulting
 - Served over 22 clients
 - Average length of engagement is 3-5 years
 - Longest engagements- 7-9 years
- <u>https://www.linkedin.com/in/shalakapurohit</u>

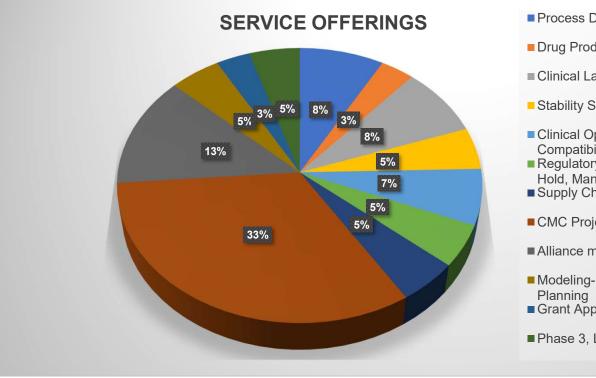




SUVEDA SOLUTIONS LLC- SERVICES

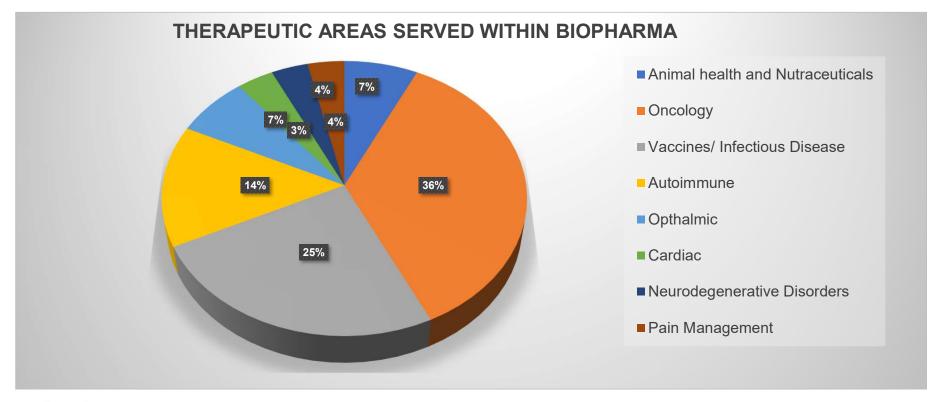
Suveda

1	СМС	 Drug Product Development and Production Clinical Label-Pack and Distribution, including QP release TPP, QTPP, Quality by design, Phase Appropriate Compliance Late Stage Development and BLA-enabling Activities
2	CLINICAL OPERATIONS	 Authoring of CMC sections for Pharmacy manuals, IBs, Dose Preparation Instructions, Stability and Expiry/ Shelf-life Programs Demand-Supply and Production Planning
3	SUPPLY CHAIN	 Ancillary Procurement and Evaluation Management of International Shipments for Critical Intermediates Distribution Strategy and Temperature Excursion Management
4	PROJECT AND PROGRAM MANAGEMENT	 Guide Strategy and Develop Program Roadmaps Right-sourcing support based on company business model Timelines, progress Dashboards, Risk and Decision Tracking
5	ALLIANCE MANAGEMENT	 RFP and Contract Service Provider Selection and Management Support Technology Transfer, Due Diligence, Acquisition transitions
6	CMC-REGULATORY	 Authoring of CMC Sections for Regulatory submissions, Amendments, Comparability, PPQ protocols etc. Management of Submission Preparation Advise and support to Address and Remedy Clinical Hold
CONFIDENTIAL		

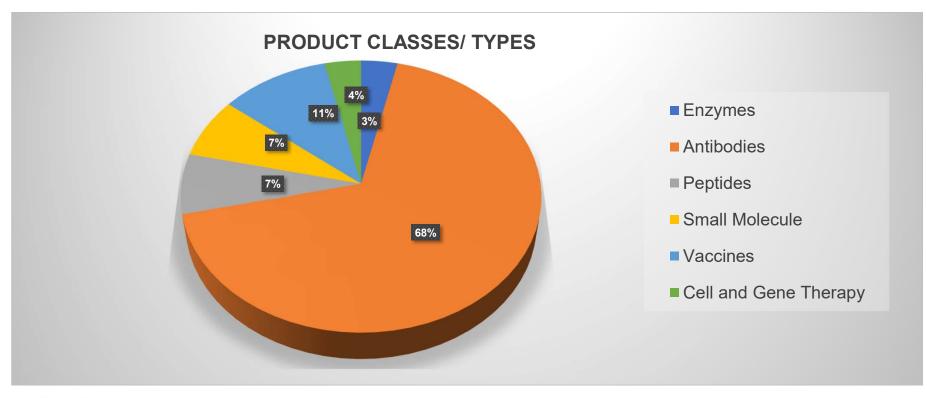


- Process Development, Scale Up Technology Transfer
- Drug Product
- Clinical Label Pack
- Stability Study and Expiry Program Design and Management
- Clinical Operation support- Ancillaries Procurement, In use Compatibility Studies, Documentation
- Regulatory Authoring- Module 3, CMC Amendment, Clinical Hold, Management of submissions
- Supply Chain- Demand supply Analysis
- CMC Project and Overall Program management
- Alliance management
- Modeling- Process, Drug Demand Supply, Production
- Grant Application Support- BARDA, NIH
- Phase 3, Late stage, BLA

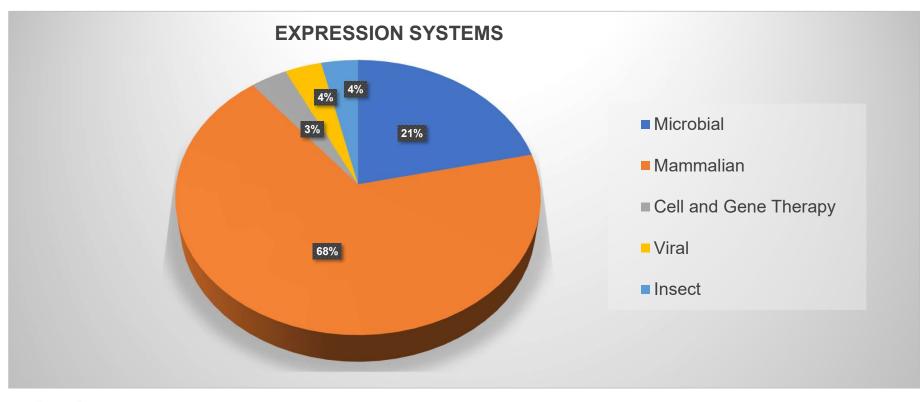














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