Suveda

know + how

Sound Advice + Superb Execution

https://www.suvedallc.com/

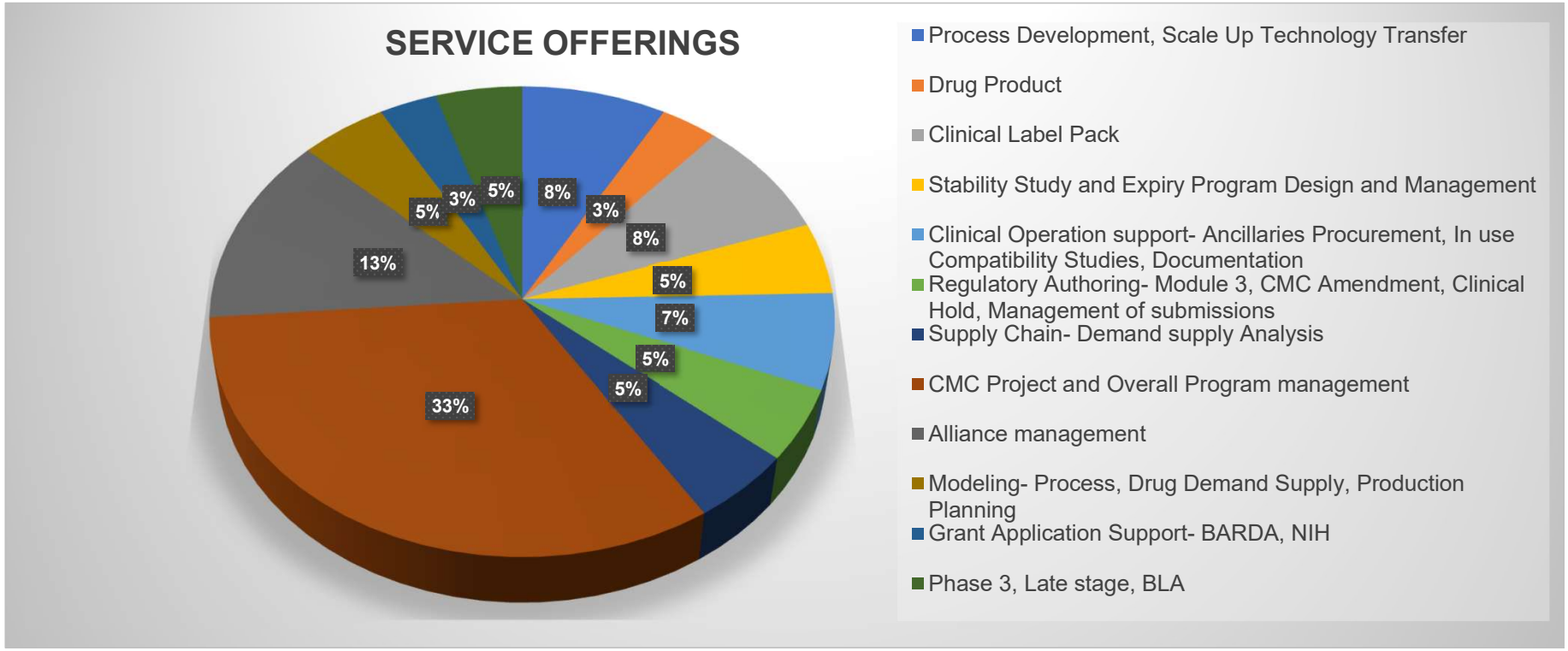
SUVEDA SOLUTIONS LLC- ABOUT US

- 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
- https://www.linkedin.com/in/shalakapurohit

SUVEDA SOLUTIONS LLC- SERVICES

1	CMC	• 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

SUVEDA SOLUTIONS LLC- EXPERIENCE



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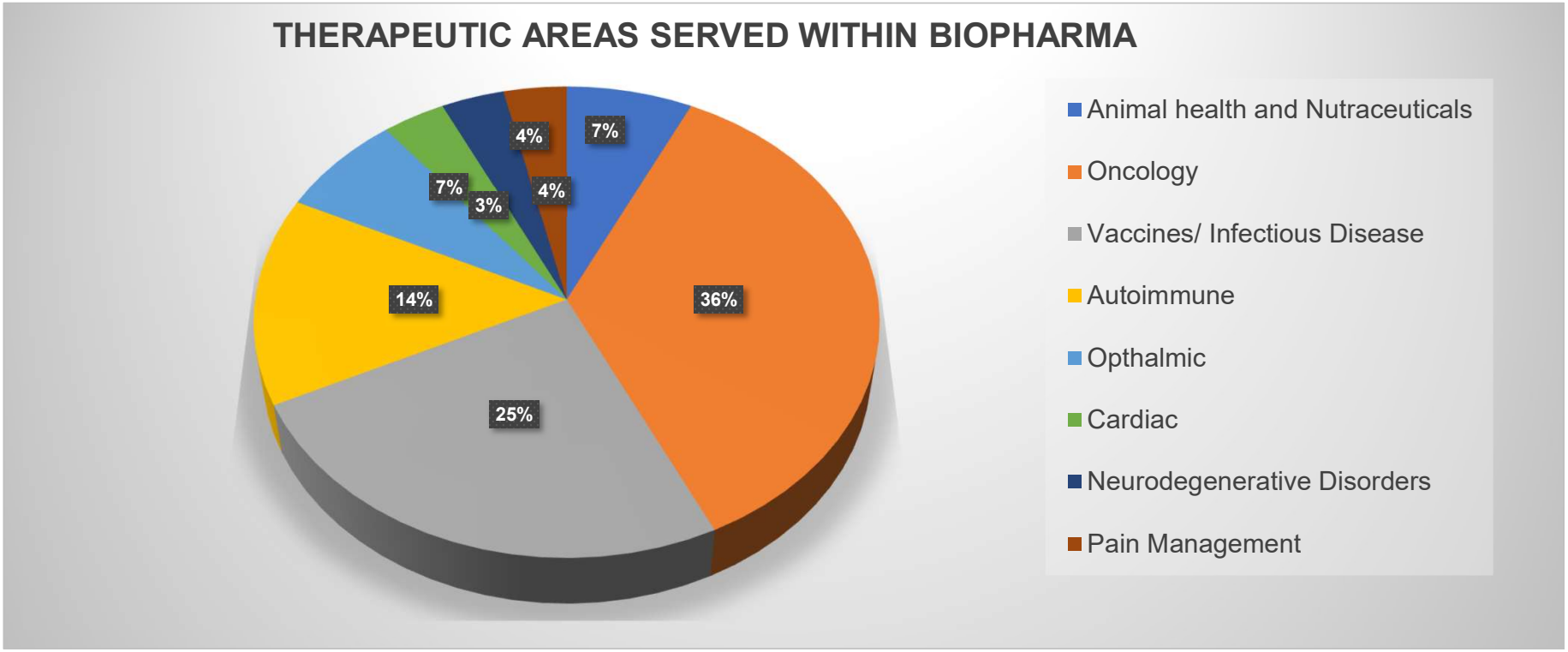

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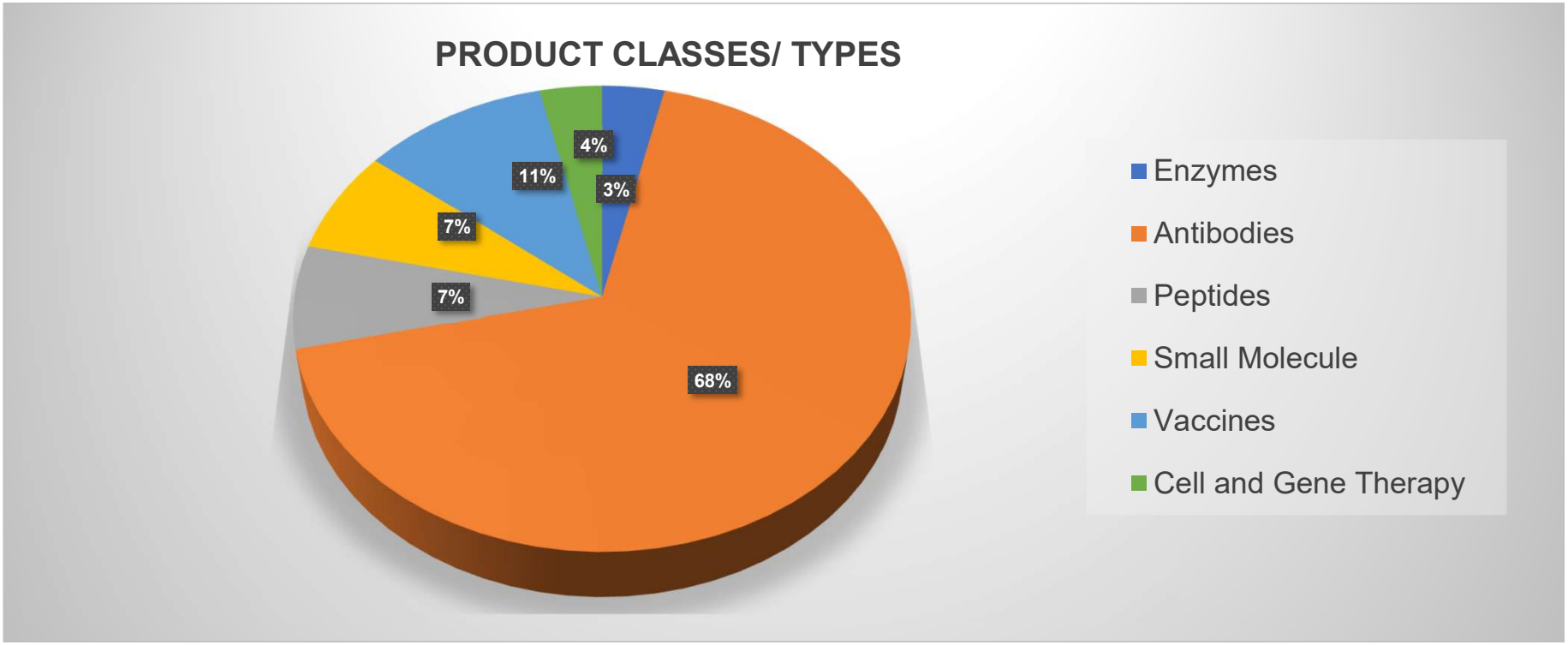

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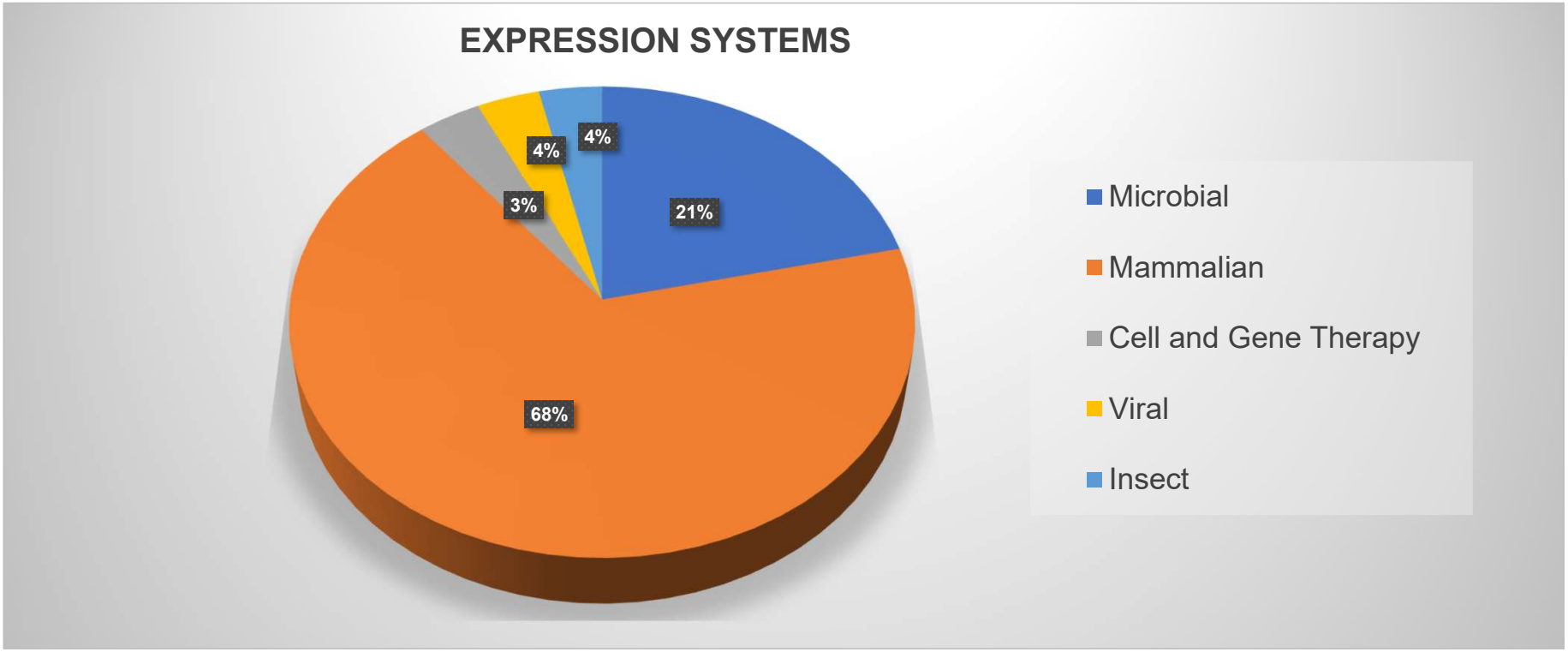

SUVEDA SOLUTIONS LLC- CONTACT US

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