Scale-Up

- Supporting biopharma, contract development & manufacturing organizations (CDMO), small businesses
- Engage small and large molecule products, biologics, cell biology, and exosome / extracellular vesicles.
- Direct operations to meet product development goals and timelines in compliance w/applicable regulations.
- Experience with design, construction, qualification, operating clinical & commercial scale facilities.
- Experience leading phase-appropriate quality operations
- Setup RFI/RFP for external CDMOs, selecting for optimal performing development and leading all activities performed by these partner companies
- Activities:
  - Product development strategies & budgets
  - Alliance/Vendor management
  - Design & construction of manufacturing facilities
  - Clinical & commercial manufacturing support
  - Manufacturing in compliance with FDA & regulatory agency interaction & meetings
  - Support IND & regulatory submissions
  - CRO & CDMO selection & oversight
  - Quality system design & implementation
  - Analytical methods development & validation
  - Manufacturing process development & validation
  - Risk mitigation & continuous improvement
  - Supply chain management & tech transfer

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