Exemplify BioPharma

Advancing Drug Development

Our team is proud to deliver original and fresh CMC Drug Development Solutions

Address: 3000 Eastpark Boulevard,
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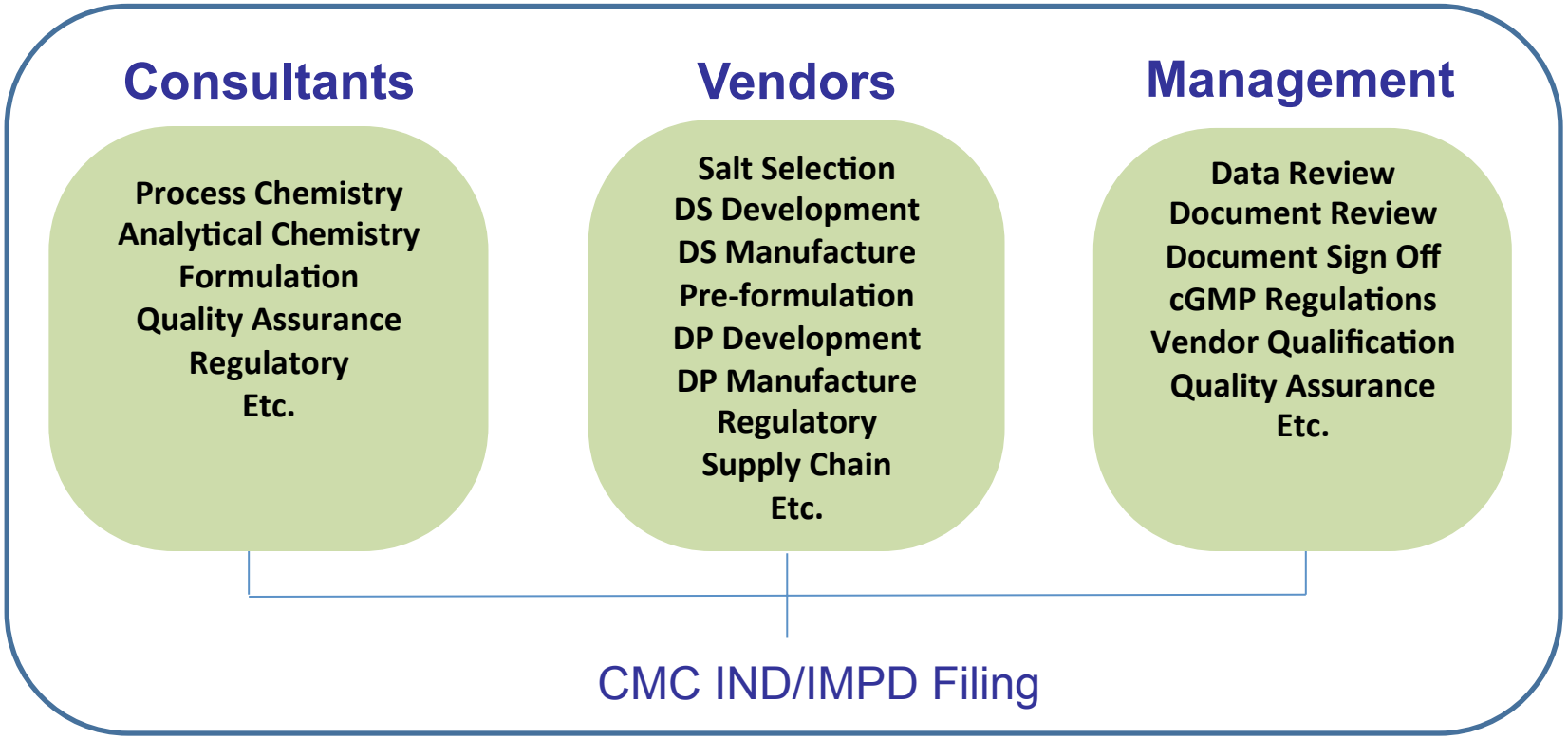
Biotech CMC Execution Model

Sponsor - Project Lead

CMC Management & Coordination



Typical Biotech CMC Execution Model is Complex, Segmented and "Vertical"

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Drawbacks to Current Biotech Model

Complexity

Multiple vendors
Multiple consultants
Budget, administrative, technical and scientific management

Silo Approach

Functional experience resides at individual CRO's
Lack of cohesive CMC
No cross functional interaction

Inefficient

Multiple points of contact
Slow timelines
Slow issue resolution

Communication

Complex-multiple vendors, time zones, languages etc.
No cross talk between functions

Expensive

Multiple consultants
Multiple vendors
Repetition
Little or no value added

Knowledge Gap

Lack of CMC end to end experience
Limited specific functional experience
Knowledge resides at CRO's

Sporadic & Inconsistent

cGMP
Quality Assurance
Regulatory
Specifications

Current Biotech Model Fails to Deliver Value in Many Ways

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Exemplify BioPharma End-To-End CMC

Development Candidate Selection- Progression Through Development

Sponsor

IND/IMPD NDA/MAA Submission

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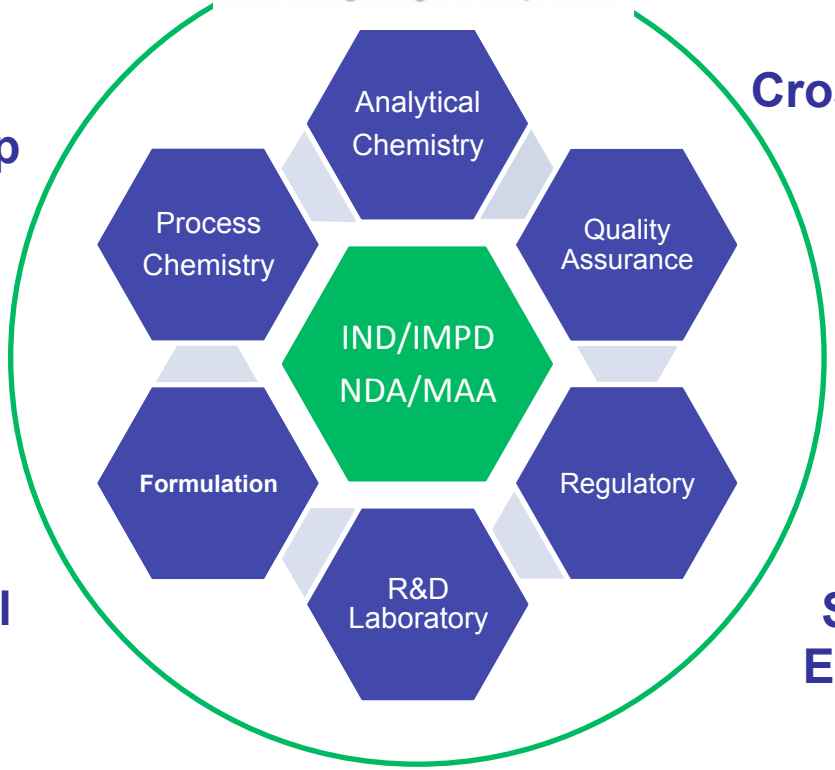
Program Leadership

Cross Functional Expertise



Functional Expertise

Scientific Excellence

First in Class Business Model

Exemplify BioPharma Model

Single Point of Contact

Exemplify will manage complexity
CRO selection & oversight in accordance with client guidance

1

2

Total End to End Coordination

Appropriate technical package for regulatory filing

Complete Cross Talk

No silo's
All functions within Exemplify
Fluid issue resolution

3

4

Simple Update/Feedback

Simple update/feedback to client with seamless project iterations

Functional Excellence

Scientific expertise and consulting in-house under one roof
Considerable cross-functional expertise

5

6

R&D Support

Exemplify R&D Laboratory
Client preferred CRO

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First in Class Business Model

Exemplify R&D Laboratory

4,500 sq. ft. R&D Laboratory

Process Development

Analytical Development

DS/DP Release Testing (cGMP)

Full compliment of cGMP Analytical instrumentation including UPLC-PDA, HPLC-ELSD, HPLC-MS, GC, SFC

Princeton University (access program): NMR, TOF-MS, GC-MS, TQ-MS

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Why Exemplify?

Project Execution

Leadership >100 programs
Diverse therapeutic areas
preclinical through phase III
Supply chain management

Scientific Excellence

>100 publications & patents
Internal R&D capability
API development
Preformulation
Formulation development
cGMP analytical

Regulatory

>100 INDs/IMPDs filed
>50 NDA/EMA filings
Type B/C meetings with FDA

- **Partners, not contract lab**
- **We know what needs to be done and how to bring your program to the next milestone!**
- **Delivering the CMC capabilities of large Pharma to a flexible and fast paced Biotech environment**

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Our Team

Yadan Chen
Analytical Chemistry

Yadan has more than 20 years of experience in New Chemical Entity (NCE) drug development. During her 20-year tenure at Merck, Yadan has led the development and successful NDA/MAA filings of several novel drugs including *Emend (Aprepitant), Taranabant (CB1), Januvia (Sitagliptin) DPP-4) and Vintafolide,* a small molecule drug conjugate.

Dr. Paul O'Shea
Process Chemistry

Paul has more than 25 years multidisciplinary experience in CMC drug development in the pharmaceutical industry. At Merck Paul led the transition of numerous programs from late stage lead optimization through to FIH clinical studies, including clinical candidates in HIV (NNRTI), Asthma , Hypertension, Diabetes and Osteoporosis.

Dr. Allen Ritter
Regulatory CMC

Allen has more than 30 years of international drug development and chemical manufacturing experience at Eli Lilly and Endocyte. Allen supported the registration of Tadalafil and Duloxetine and provided technical support for the commercial production of Gemcitabine, Fluoxetine, Pergolide, Raloxifene, and Loracarbef.

Paul Johnston
Quality Assurance

Paul has over 25 years of QA oversight experience in Pharmaceutical API and Drug Product manufacturing, packaging, testing and distribution at Schering Plough and Merck. His Audit and Regulatory Inspection experience spans US, Europe, Asia Pacific and Latin America. Paul was the R&D QA Lead for PAIs, including Peg-Intron, Clarinex, Asmanex, Temodar, Zetia and Dulera.

Jan-Jaap Scherpbier
Regulatory CMC EU

Jan-Jaap has more than 25 years of experience in Formulation and Analytical Development and Regulatory Affairs at Teva, Organon, Schering Plough, and Merck. Jan-Jaap was involved in the creation and filing of regulatory submissions for numerous products including Saphris, Bridion and Implanon-NXT and life cycle management for Nuvaring and Remeron.

Dr. Scott Reynolds
Formulation

Scott has more than 30 years experience in formulation, vaccine and chemical development in the pharmaceutical industry.
At Merck Scott led early and late stage API programs, solid oral dosage formulations, and parenteral products for small molecule, peptides and vaccines. Scott has extensive experience in development for sterile/liquid products and scale-up and technology transfer.