Regulatory Affairs

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Helping you achieve your goal of commercialization

One of the benefits of partnering with us is our ability to support you from start to finish, including regulatory submissions and support. Our role providing in-house manufacturing for a clinical-stage biopharmaceutical company enables us to share firsthand knowledge of the regulatory pathway and provide guidance outside of the realm of a typical CDMO.

Our regulatory team has extensive experience in helping clients develop the regulatory strategy and approach, including drafting responses and assisting in formulating strategies for interactions with regulatory authorities.

Regulatory services we provide:

- Comparability assessment
- Amendments
- Supplements
- CMC gap analysis
- IND/BLA/IMPD submissions
- Assistance with response to FDA questions