TLI Development

A Pharmaceutical Support Service Company

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Regulatory Affairs:

- IND/ NDA/ ANDA/ BLA/ PLA/ ELA/ DMF/ CTX/ MAA Preparation & Review
- Analytical Methods & Validation Report Review
- Specifications Development & Review
- Product Development Reports
- Stability Testing Protocols & Stability Summaries
- Prescribing Information/ Labelling Preparation & Review/ Advertising

Medical Writing:

- Preclinical Reports - Compilation & Review
- Clinical Protocols
- Informed Consents
- Study Reports
- External Publications
- Investigator Brochures

Quality Assurance:

- cGMP Audits
- Mock Pre-Approval Inspections (PAI)
- SOP Reviews/ SOP Writing
- Product/ Process Reviews
- DEA/ Controlled Substances Audits & Compliance

Biosimilars Support - Overview

Robert Zeid, the Principal Consultant at TLI Development, has been at the forefront of the biosimilars field since 1999. The concepts elucidated in his seminal article, Regulatory and Development Issues in the Demonstration of Therapeutic Equivalence for Multisource Biotech-derived Pharmaceuticals (*Drug Information Journal* 34; 919-939, 2000) were foundational to the pivotal framework guidelines adopted by the European Medicines Evaluation Agency (EMEA) and the FDA.

Over the last 14 years, he has presented and written extensively on the topic, including contributions at the FDA/DIA Scientific Workshop on Follow-on Protein Pharmaceuticals (Feb 15-16, 2005), as well as the DIA/EMEA Joint Workshop on EMEA new guidelines for development and approval of biosimilars (Dec 8-9, 2005).

He was also a member of the USP Complex Active Project Team and the Generic Pharmaceuticals Association (GPhA) Biotechnology Technical Advisory Committee (TAC).

He has worked behind the scenes with numerous firms on their biosimilar development programs, further evolving the concepts of structure-activity relationships (SAR) and evaluations in bioassays to determine the level of assay sensitivity compared to impurity levels and degradants. By applying Quality by Design (QbD) and Process Analytical Technology (PAT), he has developed more robust comparability protocols that reflect process parameters impact on SAR, as well as identifying the 'edge of failure' for certain product quality parameters. These concepts are detailed in a presentation provided in the Presentations page of this site, called Paradigm Shift in Comparability Assessment: How Quality by Design (QbD) and Process Analytical Technology (PAT) can improve Structure-Activity Relationship (SAR) evaluation and its relevance to comparability protocols and biosimilars.

The Affordable Care Act (ACA) of 2010 may have codified the 351(k) regulatory route for biosimilars, but the route to demonstrating therapeutic equivalence is still muddy for many.

TLI Development can help you with your program, be it comparability protocols, FDA meeting packages, or writing up reports.