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

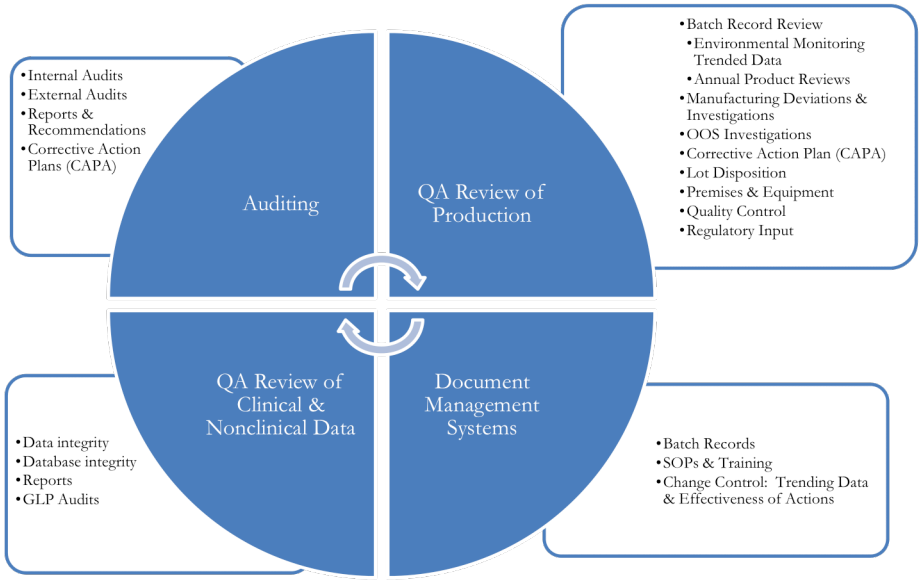
Quality Assurance:

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

Quality Assurance (QA) Support - Overview

Quality Assurance (QA) support is critical to the manufacturing and clinical development programs. Too often, companies proceed with long-range plans without confirming suitability of vendors, justification of specifications, product reviews, and more … all leading to the same result: delays and additional cost.

The schematic below shows how QA is roughly partitioned into four major areas: auditing, review of production records, document management, and review of clinical and nonclinical data.



TLI Development has provided QA support for firms of all size, ranging from very specific tasks (e.g., audits) to setting up an entire program. A list of key quality-related activities that we can support include:

- **Specifications for API & finished product:** prepare change-controlled, QA-released documents with justification of specifications
- **COAs:** prepare and sign off on client-controlled COA documents for API and finished product
- **Master Production Batch Records (MPBR):** provide QA review and sign off in addition to the manufacturing director at client
- **Executed batch record review:** provide QA review and sign off in addition to the manufacturing director at client
- **Product reviews:** can pull together data for reports
- **Audits:** can perform QA audits of the critical starting materials, API, and finished product sites with detailed reports
- **SOPs:** write, review, and manage SOPs; aid in training and scheduled reviews
- **Change Control:** review change controls from manufacturers and provide QA sign off
- **OOS Investigations:** provide an client QA review of the OOS data and investigations from other vendors; manage an in-house database
- **Quality Manual:** Help write Quality Manual