current Good Development Practice TIPs

PHARMACEUTICAL ADVISORS
Solutia Pharmaceutical Services Division

Practical advice on drug development from Solutia Pharmaceutical Advisors' leading industry consultants and senior executives with hands-on experience in bringing drugs to market.

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Get a Practical Perspective on Facility Audits for Risk-Based cGMP

With the FDA moving to "a science- and risk- based approach to product quality regulation.....", consider involving auditors with operations experience as well as experience in auditing.

Many auditors have a strong background in quality systems but may have limited experience in practical implementation or relevant science associated with risk management.

This practical perspective can help you develop workable solutions to observations, avoid unnecessary regulatory activities, provide practical implementation of cGMP. It can also build strong relationships with outsourcing partners and demonstrate that you are committed to cGMP.

Scaling up High-Potency Manufacturing Safely and Efficiently

Consider involving broad perspective on all the issues associated with scaling up and running manufacture of potent materials to avoid unnecessary containment expense.

Failure to include all the right pharmaceutical toxicology, industrial hygiene, engineering, design and process chemistry perspectives early in the process can lead to over specification, excessive capital and operating costs in processing and handling.

Performance-based OELs and inclusion of the right expertise early on can ensure safety without compromising expense or process efficiency.

Drug Substance and Drug Product go Hand in Hand with Tox Plans

If you encounter difficult toxicology issues that may call for further testing, it pays to also conduct a review of the status of your drug substance AND drug product plans concurrently.

Failure to link drug toxicology plans with plans for drug substance and drug product development when addressing toxicology challenges can come back to surprise you later.

Concurrent review can ensure that work required to develop the final bulk form or drug product will not result in additional toxicology work and delay, saving both time and expense.

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