

Perhaps the most challenging element of mitigating compliance risk throughout the R&D life cycle is ensuring compliance controls are appropriately integrated across functional areas, studies and R&D facilities. Below are just some of the key agency requirements with which companies must comply.

- *FDA Good Laboratory Practices (GLP)*
- *US Department of Agriculture (USDA)*
- *Drug Enforcement Agency (DEA)*
- *Nuclear Regulatory Commission (NRC)*
- *Occupational Safety and Health Administration (OSHA)*
- *International Conference on Harmonisation Good Clinical Practices (ICH GCP)*
- *European Union Clinical Trial Directive (EUCTD)*

How does your organisation ensure compliance with these and other regulations impacting R&D?

How can pharmaceutical and life sciences companies sustain effective regulatory compliance throughout the R&D process?

Pharmaceutical and life sciences companies are looking for new ways to improve productivity within their research and development (R&D) organisations to improve their product pipeline. While companies work to tackle the productivity issues through operational and organisational change, the Food and Drug Administration (FDA) and other regulatory entities continue to raise the bar regarding the scope of compliance efforts requisite to manage the risks inherent in R&D processes. Process improvement efforts to more quickly and efficiently bring molecules from bench to bedside necessitate greater financial investments from companies across the discovery, pre-clinical research and clinical development stages. As companies invest in new approaches for conducting and managing both the research and development processes, traditional methods of assessing compliance may not adequately address all of the compliance risks within R&D.

While most companies are equipped with a Quality Assurance (QA) function with auditing capabilities, resource constraints and QA's limited scope of responsibility often do not allow this function to comprehensively address regulatory compliance needs across functions, sites and studies. To meet increasing R&D regulatory compliance challenges, pharmaceutical companies must consider expansion of existing compliance programme elements to include R&D activities.

Pre-clinical research compliance issues centre on study-related activities within the laboratory environment, including study planning and coordination; acquisition, care and use of animals; purchase, use and disposal of controlled substances and radioactivity; QA unit activities; and the oversight of contract laboratories. In clinical R&D, the organisation's compliance focus shifts to activities such as patient recruitment, site selection, managing CROs, case report form processing and serious adverse event reporting.

How can PwC help your organisation?

PwC's pharmaceutical R&D compliance professionals leverage their R&D experience using a proven risk and compliance assessment methodology and include:

Compliance controls assessment – PwC can help your organisation assess its existing compliance control environment and identify gaps where policies and procedures, training, systems, auditing and monitoring may not be effectively mitigating business and compliance risks.

Process and controls harmonisation – As organisations undergo process and organisational changes and expansion, they must ensure that new R&D practices are compliant and that compliance controls are effective. We can work with you to develop a plan to review and redesign key processes, identify existing controls and gaps, and implement processes and controls that you can apply consistently across the organisation.

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Risk and compliance monitoring – PwC can help you tailor your compliance programme to more effectively identify, evaluate, manage and mitigate risks. Through a systematic approach, we can work with you to identify the risks and compliance issues that your organisation would want to monitor proactively. We can work with you to identify key performance indicators of your compliance controls and other measures of operational, technical and business risk impacting your R&D functions.

Benefits you can realise

Improved quality of regulatory submissions through adherence to FDA GLP and ICH GCP guidelines

Appropriate compliance controls supporting data quality, data handling, record keeping, and archiving for both pre-clinical and clinical research

Ability to mitigate the risk of future regulatory inspection findings such as: FDA-483 violations, OSHA violations, USDA violations, and Medicines and Healthcare Products Regulatory Agency (MHRA) findings

Consistency in your R&D compliance controls across various geographies where pre-clinical and clinical research is conducted

Why PwC succeeds where others fail

Our Pharmaceutical and Life Sciences Practice comprises more than 2,100 industry-focused specialists worldwide. Because R&D is a highly regulated and process-intensive field, PwC has built a practice that includes individuals with in-depth experience in regulations and compliance, as well as performance improvement, to ensure you meet all your unique R&D compliance challenges. No other professional services firm provides a more comprehensive combination of top-flight qualifications, thought leadership and ability to deliver effective, industry-focused R&D compliance advisory services.

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Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 161,000 people in 154 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.