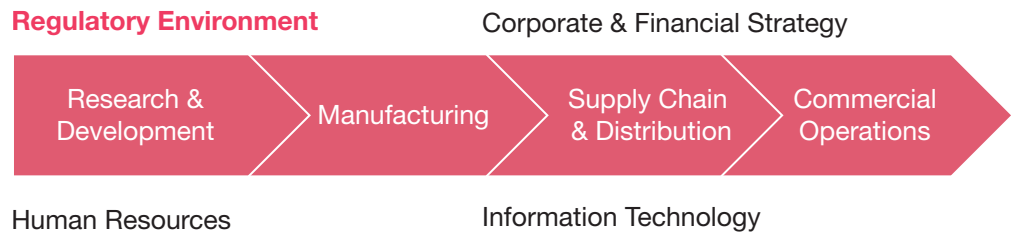


## Ensuring regulatory compliance: a complex and risky process for your organisation



### Benefits

- Creating business benefits and protecting the company brand
- Sustainable and consistent compliance monitoring programmes
- Increased data consistency and quality as information is sourced, transformed, managed and distributed to address monitoring reporting
- Reduced risks in regulatory inspections
- Business risk reduction by optimised compliance

At every part of the product life cycle, from R&D through manufacturing, distribution and marketing of products, pharmaceutical and life sciences companies must adhere to regulations from local, national and international authorities. Ensuring regulatory compliance at every level in multiple territories around the world is a complex and risk-laden process.

### How can PwC help you?

PwC recognises the complexity of the different regulatory & compliance requirements on local and international levels. Our governance, risk & compliance advisors throughout the globe work closely together on local and international regulatory and compliance challenges which the pharma and life sciences industry is currently facing:

*Regulatory compliance assessments, implementation and improvement in the area of:*

- GxP (GCP, GMP, GLP)
- Sales & marketing compliance — (a.o. deontological interaction with healthcare practitioners)
- Pharmacovigilance
- ICH Q8, Q9, Q10
- e-CTD
- IT Compliance (a.o. Computer Systems Validation)

*Regulatory affairs and compliance strategies of the future aligned with the business vision and innovative concepts such as PAT/QbD, continuous manufacturing, disposable manufacturing concepts, etc.*

*Global integrated compliance programmes*

*Enterprise risk management programmes*

*Specific compliance requirements for medical devices, blood fractionation, biotechnology, diagnostics, nutraceuticals, etc.*

*Support-consistent application of policies and regulations in diverse operating environments and geographies*

*Making data accessible for real-time investigations, audits and monitoring*

*Regulatory & compliance audits*

## Contacts

### Ingrid Maes

Director  
ingrid.maes@pwc.be  
+32 (0) 3 259 3305

### Nico De Backer

Principal Advisor  
nico.de.backer@pwc.be  
+32 (0) 9 268 8395

## Proven experience

### Client issue

*The pharmaceutical company was subject to a government fine (\$m), operational restrictions and potential reputational damage due to compliance violations in its R&D and manufacturing operations. The company requested PwC's support with their quality & compliance management programme including the process assessment, risk assessment, prioritisation, remediation and on-going monitoring of the different compliance processes and the different in-house technologies.*

### PwC solution

*PwC leveraged its subject-matter experts in R&D, manufacturing and sales compliance to help the company identify its compliance risks and gaps throughout the organisation. The compliance review was based on interviews with key personnel, a review of standard operating procedures and validation deliverables, compliance risk assessments and workshops and compliance gap analysis. The final deliverable included a report of key observations and recommendations. Based on this report a remediation plan was built and implemented.*

### Benefits

*This project helped the client identify the areas of risk and compliance gaps in R&D, manufacturing and sales & marketing operations. Due to the extensive involvement of personnel and management, better awareness was created of the different risks, gaps and required controls. Finally, we helped the client to implement the remediation plan (update of SOPs, CAPA plan, good documentation practices, etc.).*

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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.