

Abstract

Managing Risk in the Pharmaceutical Outsourcing industry in China:

The role of Organisational Capability building as a complement to GMP and “technical” risk management capabilities

Pharmaceutical manufacturing remains one of the world’s most profitable industries but is under increasing price and margin pressure from ever more cost conscious Governments and customers. One important strategic response to this has been to outsource parts of the Supply Chain to suppliers and partners in Asia. Whilst such a strategy may combat the margin pressure, it does so at the cost of increasing actual or potential business risk, especially as many of these Outsourcing Partners in Asia are at a relatively early stage of organisational maturity.

Outsourcing carries many risks, whether in the form of Regulatory and Compliance or Reputation and Supply, and this is a potentially game changing strategic variable that requires the highest level of management attention. Most Pharmaceutical multi-nationals devote considerable time supporting and auditing their outsourcing Partners’ compliance and regulatory processes. Many even place their own specialists on-site to help develop local capabilities to help assure good risk assessment outcomes at critical points in the development and manufacturing cycle.

In our experience however, developing the capabilities to manage the above risk dimensions also requires a focus on building broader Organisational and Leadership capabilities within these Partner Organisations.

This is why at Janssen Pharmaceuticals (Johnson & Johnson) we have developed and implemented several new processes for supporting and developing Partner Organisations in 4 additional domains:

- Strategic Leadership
- Communications Effectiveness (between the Partners)
- Organisation and People Development
- Financial Health

We engage with our Partners in the above areas through a series of structured interventions, including holding workshop events with their extended management teams and senior executives from Janssen.

We manage this process for the long term and take the view that building these capabilities in our Partners’ organisations represents an excellent return on the heavy investment we are making, both in terms of \$’s and our Reputation. Helping our Partners to develop these broader Strategic and Organisational capabilities is an excellent way to reinforce the more short term focus of ensuring “technical” and regulatory compliance capability.

This paper/presentation will present the case for, and the application of, such processes with two API Partners in China. We shall also outline the progress and some of the results achieved in their development over the last three years.

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