

Neil Wilkinson reflects on the In-House Quality Certification Training at Roche

The Pharmaceutical Industry continues to go through an unprecedented rate of change, driven by socio-economic, fiscal and globalization factors. This level of change is here to stay for the foreseeable future.

For many of us these are challenging times, with mergers, acquisitions, plant closures and a new focus on emerging markets being very visible consequences.

Regulators are acutely aware of the distractions this can pose and the potential for increased risk of product quality and supply issues. Enforcement activities have again become more frequent and high profile, often with a focus on how companies deal globally with issues.

All of the above are occurring at a time when pharmaceutical regulations and guidelines are being written or updated at an astonishing rate. How do we keep current?

So, how do companies respond?

Slash budgets and suspend training for several months (by which time those responsible will have moved on, leaving behind a legacy for others...)

OR

Protect the company reputation and try to embed a true quality culture whilst developing key personnel for the future



Neil Wilkinson



Roche has chosen the latter approach!

Following the integration with Genentech, the Quality Certification Program (QCP), which has been running in the US for 3 years, has now been expanded to add a parallel program based in Basel, Switzerland.

Roche's strategic aim is to embed a strong quality culture and leadership base alongside a harmonized global quality system, deployed across its global operating locations, to drive the appropriate level of consistency.

As well as being a great source of learning for individuals, the QCP also helps break down any silos that exist between different sites, functional groups or even previous companies, and establishes a strong network of catalysts for change/improvement.

QCP delegates undertake multiple modules within the duration of the program. The modules are customized for Roche, based largely on the education requirements for the Qualified Person in Europe. Graduation criteria for the program are agreed between Roche and NSF-DBA and include individual assessments, work projects and a final panel presentation.

The picture above shows the first Roche QCP group in Basel, along with Neil Wilkinson and Peter Smith from NSF-DBA. The group includes representatives from multiple Roche locations around the world.

So, what will the response of your company be?

Contact Neil Wilkinson at njw@nsf-dba.com if you wish to learn more about our in-house programs