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## Risk based intercultural property assessment

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IP protection is of paramount importance in the pharmaceutical industry, particularly during outsourcing. As a leading CRO, we are working very hard to quantitatively identify the IP gaps in our GMP practices so they can be managed accordingly. In this presentation, principles from ICH Q9 to assess the integrity of our IP system, and some of the weakness we see and the challenges we face to improving IP in GMP area at WuXi Apptec, a major contract research organization (CRO) in China (Asia) will be discussed. A methodology implemented that may be useful to others in the industry as well to assess their IP status will also be discussed.

## Biography

Jerry Xu is Vice President of GMP QA and US Regulatory Affairs at WuXi Apptec. Before joining WuXi Apptec, he spent 25 years in the US. He has 20 years of experience in the pharmaceutical industry. His previous job was a CMC reviewer with the US FDA. He received his PhD in Organic Chemistry from Northeastern University.

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