

Residual Solvents: A PhRMA Perspective
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Controlling levels of residual solvents in pharmaceutical products has been an expectation of regulatory authorities since 1998 for new product registrations in the three ICH regions and since 2000 for all products marketed in Europe. ICH guideline Q3C presents a toxicology-driven approach to ensure patient safety and provides regulatory consistency across geographical regions and markets.

This presentation discusses experiences of pharmaceutical manufacturers in implementing the ICH guideline and our perspective on extending the benefits of this guideline to encompass all pharmaceutical products marketed in the United States.