


XENOTECH
A BioIVT Company

Regulatory Compliance

## *Ensuring Your Study Design is Based on Regulatory Expectations and Sound Science*

When assessing your compound development strategy, it is essential to understand where you are going and how you are going to get there. Whether it is explaining results from a study to plan your next move, or guidance about regulatory expectations, XenoTech's DDI and drug metabolism experts can provide the strategy behind the science.

For instance, in 2017 the FDA released its new draft guidance for industry on drug-drug interaction (DDI) studies. As the FDA's previous draft DDI guidance was issued in 2012, stakeholders needed to adapt quickly to meet the FDA's new expectations. Needed changes, however, cannot occur without consideration. Relevant questions such as strategies to ensure the utility of recently conducted studies on clinical-stage candidates are paramount. For candidates under development for which definitive in vitro DDI studies have already been performed, it is recommended to first perform a gap analysis with respect to the differences between the 2012 and 2017 guidance documents.

### 25 Years of Global ADME/DMPK/DDI Expertise

Our consulting team has a long history of experience and unsurpassed expertise regarding metabolism-related research. Considering XenoTech's strong reputation, our team is frequently asked to consult with companies worldwide to help discover new and innovative approaches towards successful compound development. Let our team of experts move your drug development process forward with their extensive knowledge and industry experience.

Invest your time and money wisely, let XenoTech guide you in you the right direction for all your drug development needs!

### The 2017 Draft FDA DDI Guidance At A Glance

*The 2017 draft guidance includes several significant changes for in vitro DDI studies from the 2012 draft guidance, some of which we have been anticipating and including in our studies for some time now, including the following:*

- CYP inhibition: Use validated analytical methods for the marker substrate. XenoTech has used validated LC-MS/MS methods for many years.
- Reaction phenotyping: Demonstrate specificity of chemical inhibitors under the conditions used in incubations.
- CYP Induction: the endpoint can be mRNA or enzyme activity if the inhibition profile is known first. XenoTech has used both endpoints for many studies for many years.
- CYP induction: Evaluate CYP2C enzymes if CYP3A4 is induced. XenoTech has been recommending this approach for several years.
- CYP Induction: Include a clinically used negative control. XenoTech has been including a negative control for several years.
- Transporter studies: The addition of interaction studies with MATE1 and MATE2-K. XenoTech has been recommending these transporters for most studies for several years.
- Transporter studies: keep organic solvent <1% (preferably <0.5%). XenoTech has been taking this approach for many years...

For more information, please contact us at
**913.438.7450** or **info@xenotechllc.com**

## Register for our FDA DDI Guidance Webinar:

**Essential Considerations on the New FDA In Vitro DDI Guidance (the What, the Why, and the Wow)**

*Presented by Brian Ogilvie, Ph.D., XenoTech Vice President of Scientific Consulting*

## or FDA / EMA / PMDA DDI Guidance Comparison Webinar:

**Comparison Between the 2017 FDA & PMDA and 2013 EMA In Vitro DDI Guidance Documents: Are We Close to Harmonization?**

*Co-Presented by Brian Ogilvie, Ph.D., XenoTech Vice President of Scientific Consulting and Andrew Parkinson, Ph.D., XPD Consulting Chief Executive Officer*

**www.xenotech.com/webinar-series**