# QSRA Project Titles 2024/2025

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| 1.How have ICH guidelines impacted the biopharmaceutical sector in the past 20 years? | Ivana Celic  Oluwatoyin Timothy Ojo  Brian Callanan  Robert Bil  Ciaran Mulhair  Livia Candiba  Anthony McDonagh |
| **2.Do the stringent regulations in the biopharmaceutical sector negatively impact on innovation?** | **Suzan Shamboul**  **Heather Telford**  **Li Juan Ang**  **Maciej Chrabolowski**  **Veronica De Campos Folchetti**  **Ciaran Tobin** |
| **3. Is harmonisation of regulatory requirements between the EU and US in the biopharmaceutical sector likely or is it necessary?** | **Severine Pacaud**  **Conor Donaghy**  **Saoirse Quigley**  **Marcin Grawiec**  **Ronald Kayinga**  **Aoibheann Kelly** |
| **4.A review of the drug approval pathways in the EU and the USA- Which is better and why?** | **Upasika Upasika**  **Daria Shustrova**  **Bestella Zoka**  **Jenna Power**  **Bhavika Bhavika**  **Grzegorz Kowalczyk**  **Christopher Doyle** |
| **5. A review of Clinical trials regulation in the EU and USA– Are they adequately regulated and is there room to improve?** | **Brenna Harte**  **Maire Corkery**  **Beata Zoltowska**  **Marcin Swoboda**  **Agnieszka Krawczyk** |
| **6. Has the typical Quality System in Biopharmaceutical manufacture changed dramatically in the past 20 years and are these changes significant?** | **Oliver Jackson**  **Noemi Gonzalez**  **Robert Jervis**  **Jenika Hazell**  **Ivana Lukic** |
| **7. What approaches might a biopharmaceutical manufacturer take in terms of their validation projects and activities. Which approach is best and why?** | **Mark Guildea**  **Shauna Dunne**  **Ailish Dowling**  **Gavin McEnery**  **Paul Mahony**  **Doreen McNamee** |
| **8. A comparison of the traditional approach to pharmaceutical development to the Quality by Design (QbD) approach.** | **Justyna Skiba**  **Paola de Castro Calocci**  **Beatriz Alves Brandao**  **Ian Ritchie** |
| **9. How can Risk Management (ICH Q9) be best applied in biopharmaceutical development and manufacturing?** | **Brian Carig**  **Vismantas Samaska**  **Edcel Templo**  **Jemuell Salazar**  **Anji Thomas** |
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