

. **SCOPE OF THE PROPOSAL**

- . NSF Health Sciences will deliver, in English, a one day update, to commence at 09:00 and finish at 16:00, on changes to pharmaceutical legislation and guidance covering the following areas: Changes to EU Legislation:
 - The CT Regulation 536/2014
 - Implementation of Falsified Medicines Directive 2011/62/EU
- . QP API Declaration template Changes to EU Guidance:
 - EUGMPPartI:NewChapters3,5,&8
 - EU GMP Annexes 15, 16 & 17
 - CHMP Guidance on Process Validation
 - CHMP/CVMP Guideline on setting health based exposure limits International Changes
 - ICH
 - Data Integrity
 - WHO
 - PIC/S Changes to USA Legislation and Guidance · DQSA
- . · New and Draft Guidance for Industry