Panel Discussion

Viral safety of biotechnology products – changing the regulatory landscape, variation of modalities and analytical technologies

- Concerning Q5A(R2) guideline, what kind of benefits and challenges are expected in virus clearance strategies or validation approach?
  - *Is there any impact to the biologics already on the markets?*
  - *What are significant benefits ICH Q5A(R2) can offer to new product development and ultimately to our patients?*
- Are there any challenges or expectations in terms of virus clearance strategy of emerging product type/class which will be scope of revised guideline, such as AAV?
- In terms of product type with extensive experiences of manufacturing such as Mab, are there any challenges or expectations concerning flexible and alternative approach of virus clearance and validation including prior knowledge?
  - *What are the minimum requirements for prior knowledge to be accepted as substitute for product-specific viral clearance validation experiments*?
    - Industry's point of view?
    - Regulator's point of view?
    - How could Q5A(R2) help global harmonization of basic principles or minimal requirement for use of prior knowledge to claim viral clearance for new products?

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- Are there any challenges or expectations to implement alternative virus detection methods as replacement/supplement of existing assay?
  - *In Q5A(R2) draft guideline, there is fundamental shift towards omission or replacement of animal testing. NGS technologies has received a high degree of attention.*

- Are there any desirable suggestions or challenges concerning virus clearance strategies of continuous manufacturing process?