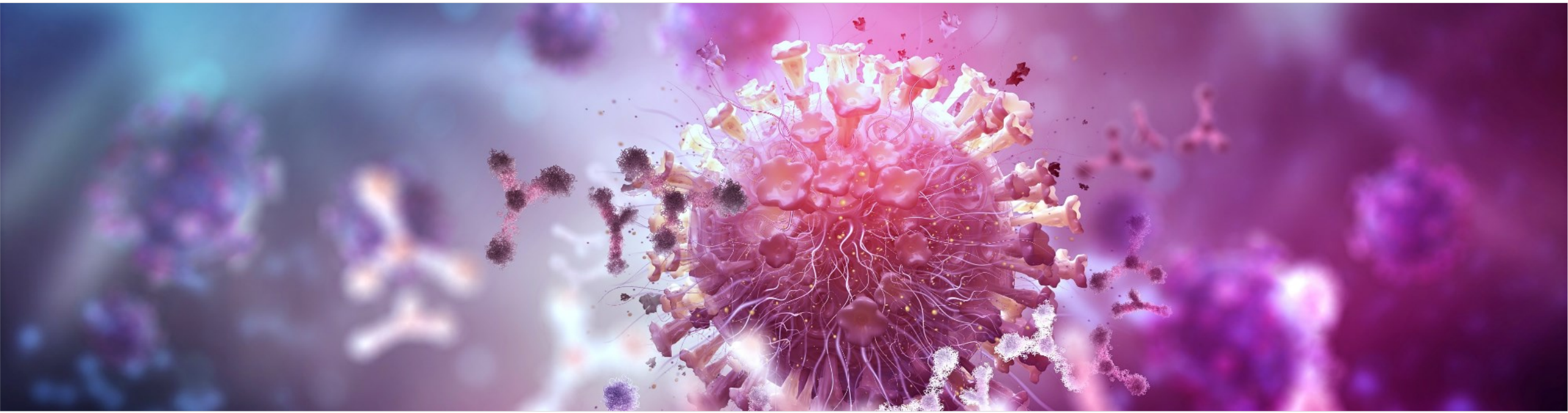


2nd ViruSure Workshop

Vienna, September 23rd, 2022

Dr. Ralf Klein, Head of Business Development

VIRUSURE
Quality is no coincidence

Revision of ICH Q5A (R1) - 1997

European Medicines Agency

October 1997
CPMP/ICH/295/95

ICH Topic Q 5 A (R1)
Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

Step 5

NOTE FOR GUIDANCE ON QUALITY OF BIOTECHNOLOGICAL PRODUCTS: VIRAL SAFETY EVALUATION OF BIOTECHNOLOGY PRODUCTS DERIVED FROM CELL LINES OF HUMAN OR ANIMAL ORIGIN
(CPMP/ICH/295/95)

ViruSure Overview

About us…


Austria (Vienna)

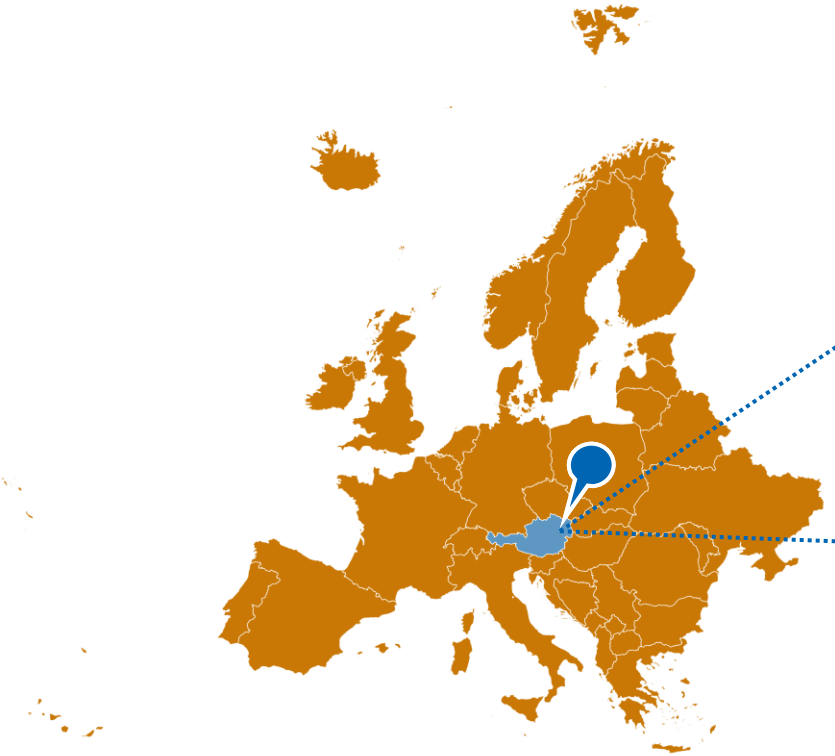

GLP/GMP certified


In vivo and *in vitro* facilities


> 17 years of expertise

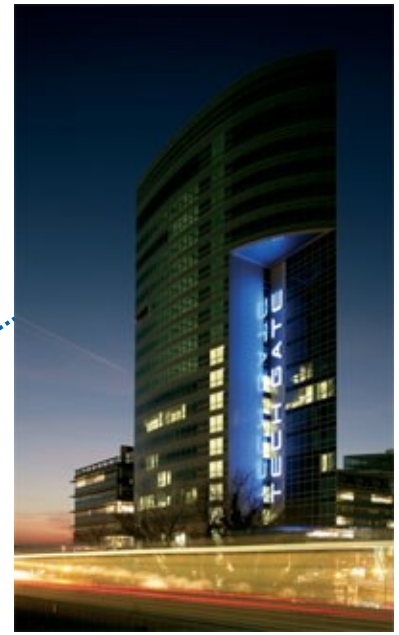

> 75 Highly Qualified Staff

Facilities – Austria, Vienna



***In vitro* Testing Facility**

Tech Gate Technology Park



Animal Facility

Boku Biotech Site

ViruSure Overview

Products We Test…

- Recombinant
- Plasma/Urine-derived
- Animal-derived
- ATMPs
- Vaccines

Our Services in a Nutshell

Cells & Virus Banks

- Banking
- Storage (GMP)
- Characterization (e.g., mycoplasma, sterility, TEM)

***In vitro* Safety Studies**

- Adventitious Agent testing
- Retrovirus Infectivity Testing
- 9CFR Bovine/Porcine *in vitro* Assay

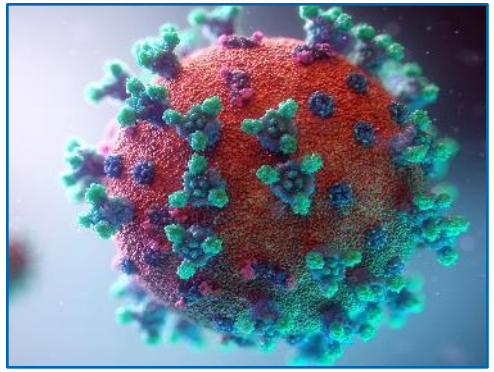
***In vivo* Safety Studies**

- Adventitious Agent testing
- MAP/HAP
- Tumorigenicity & Oncogenicity Studies
- Biodistribution Studies for ATMPs
- *In vivo* prion studies

Our Services in a Nutshell

Molecular Tests

- qPCR for Virus/Pathogen Detection (> 130 qPCR)
  Bovine, Porcine, Human, Insect, Avian virus packages
- Identity Testing
- FPERT
- Genetic Stability/Sequencing
- NGS (R&D)



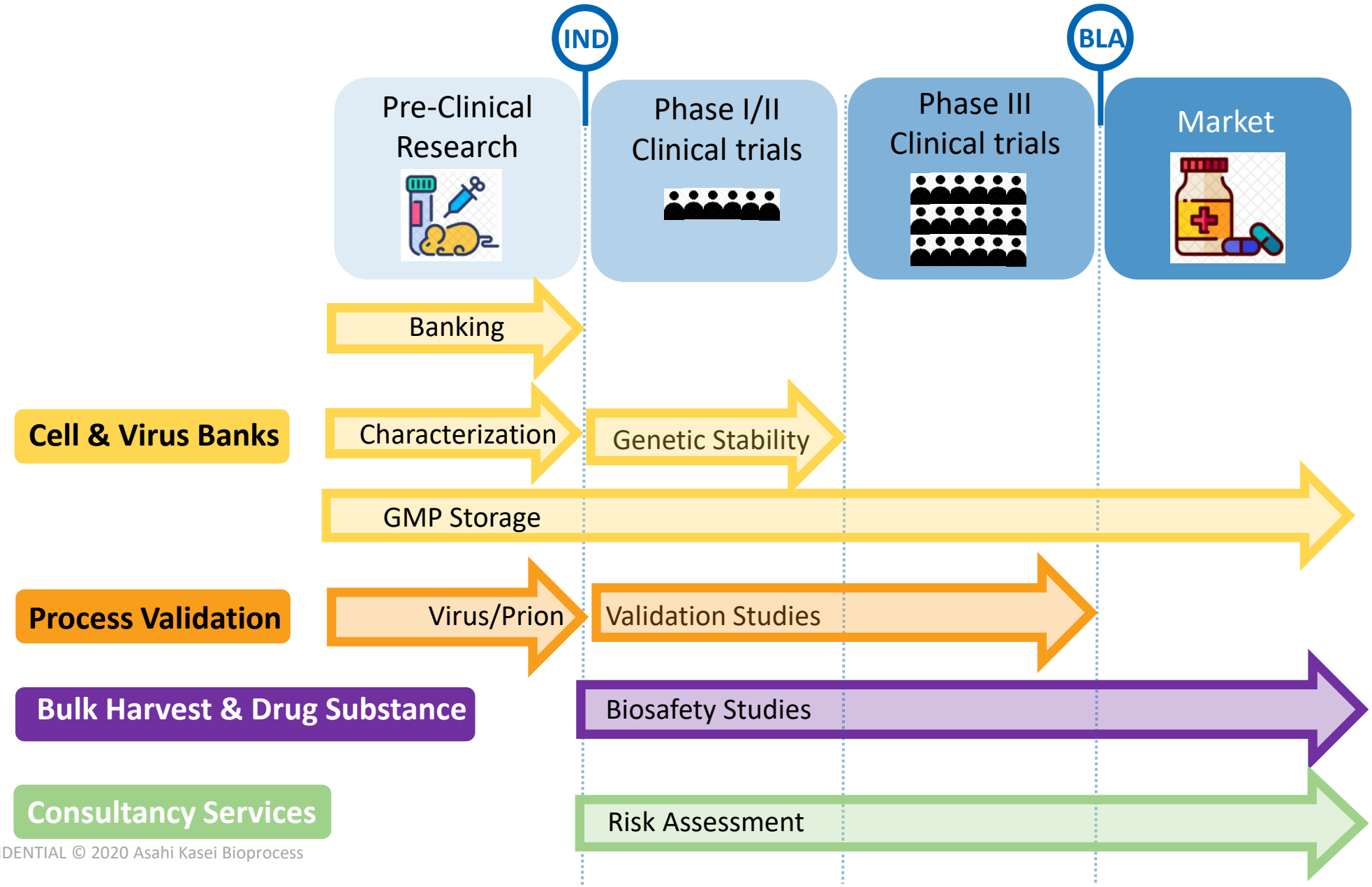
Virus/Prion Clearance Studies

- Virus Clearance studies (phase I/II & phase III clinical trials)
- Prion Western Blot Testing Services
- *In vivo* Prion Bioassays

Consultancy Services

- Biosafety Risk Assessments
- Expert Reports

When can we support you?



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Agreed Subjects of ICH Q5A Revision (Singapore Meeting 2019)

- Change of Scope - Include new classes of biotech products
  (Andy & Ralf)
- New Assays, Alternate Analytical Methods (PCR, NGS)
  (Hans-Peter & Tiff)
- Continuous manufacturing and impact on Virus Validation
  (Roya)
- Several new aspects of Virus Validation Studies
  (Katy)
- Modular approach for Virus Validation Studies
  (Ralf)

Progress of ICH Q5A Revision Process by EWG

(EWG = ICH Q5A(R2) Expert Working Group)

- Initial Nov. 2019 EWG Meeting in Singapore

  Agreement on topics for revision

- Nov. 2021 EWG Meeting in Vancouver cancelled due to COVID-19

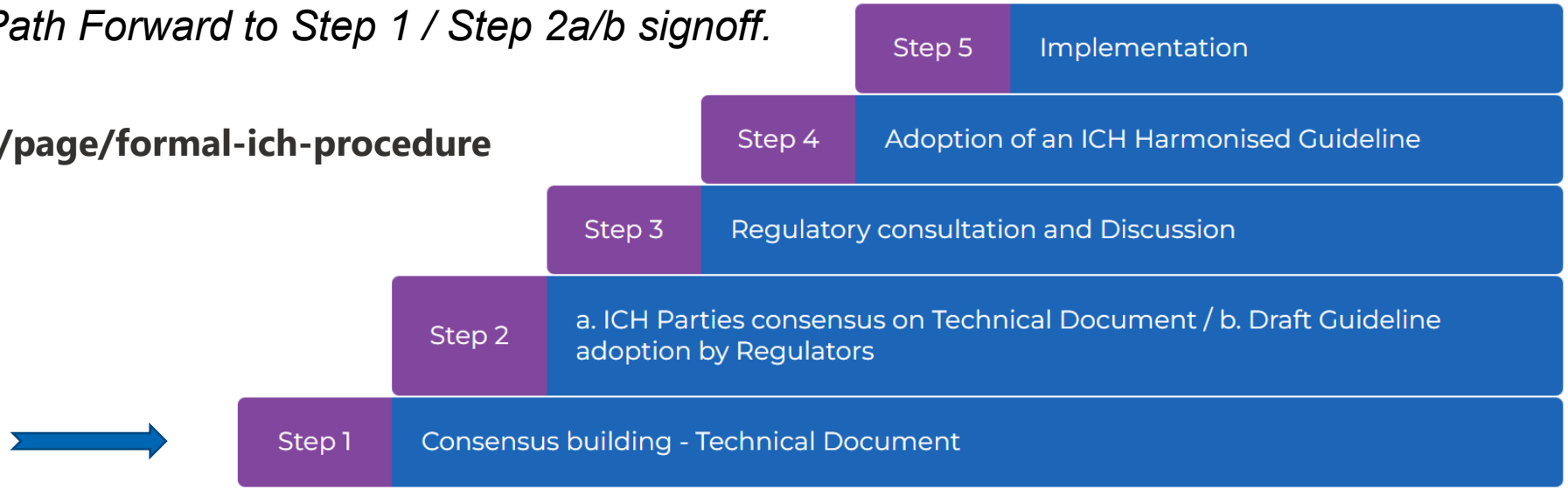
  Virtual Discussions in small EWG instead: 1068 comments/200 major.

- May 2022 Hybrid EWG Meeting in Athens

  Final editorial correction and agreement on timelines.

  Confirmed Path Forward to Step 1 / Step 2a/b signoff.

www.ich.org/page/formal-ich-procedure



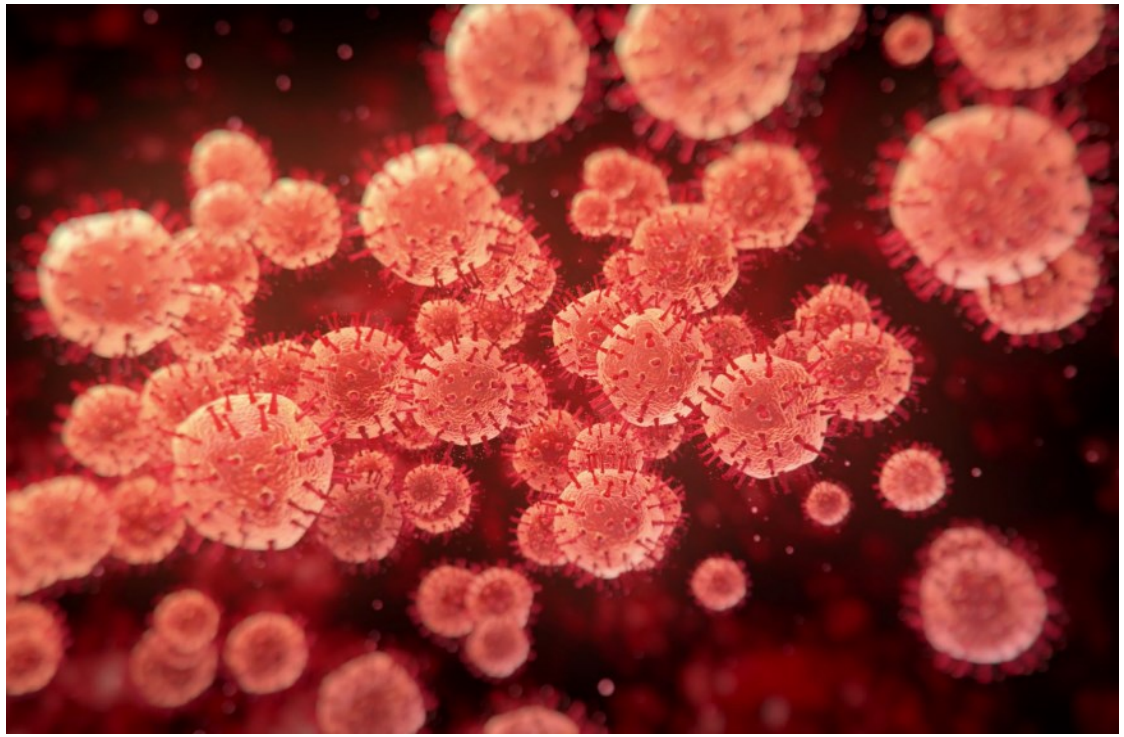
New Classes of Biotechnology Products – Extended Scope

Virus-like Particles (VLPs)

Subunit Proteins

Viral-Vector based products

for vaccines and gene therapy products using novel mammalian and insect-based vector/cell expression systems.



e.g. Baculovirus-expressed VLPs and Proteins; AAV Vectors; Adenovirus based Products

Clearance of virus vectors and adventitious agents may need be demonstrated for some of these new products.

These new product types so far have not been covered by ICH Q5A(R1)

VC studies can contribute to the safety of these products!!

Modular Approach for Virus Validation Studies

Extensive knowledge gained over the years on virus removal and inactivation with platform processes for e.g. monoclonal Antibodies (mAb´s).

- Dedicated Viral Clearance Steps have been developed.

- Virus Filtration accepted as robust virus removal method for recombinant proteins.

Prior Knowledge supporting **Modular Validaton** needs to be better defined:

- Expectations and limitations shall be discussed.
- Case studies shall be included to show level of details required.
- Principles for in house and platform data shall be described e.g. DoE approach for inactivation or filter steps.

VIRUSURE

Quality is no coincidence

감사합니다 Gracias Danke

Благодаря 谢谢 Tack धन्यवाद Dziękuję

Спасибо Thank You Obrigado

Děkuju Grazie Ευχαριστώ Merci Köszönöm

ありがとうございました Teşekkür ederim