

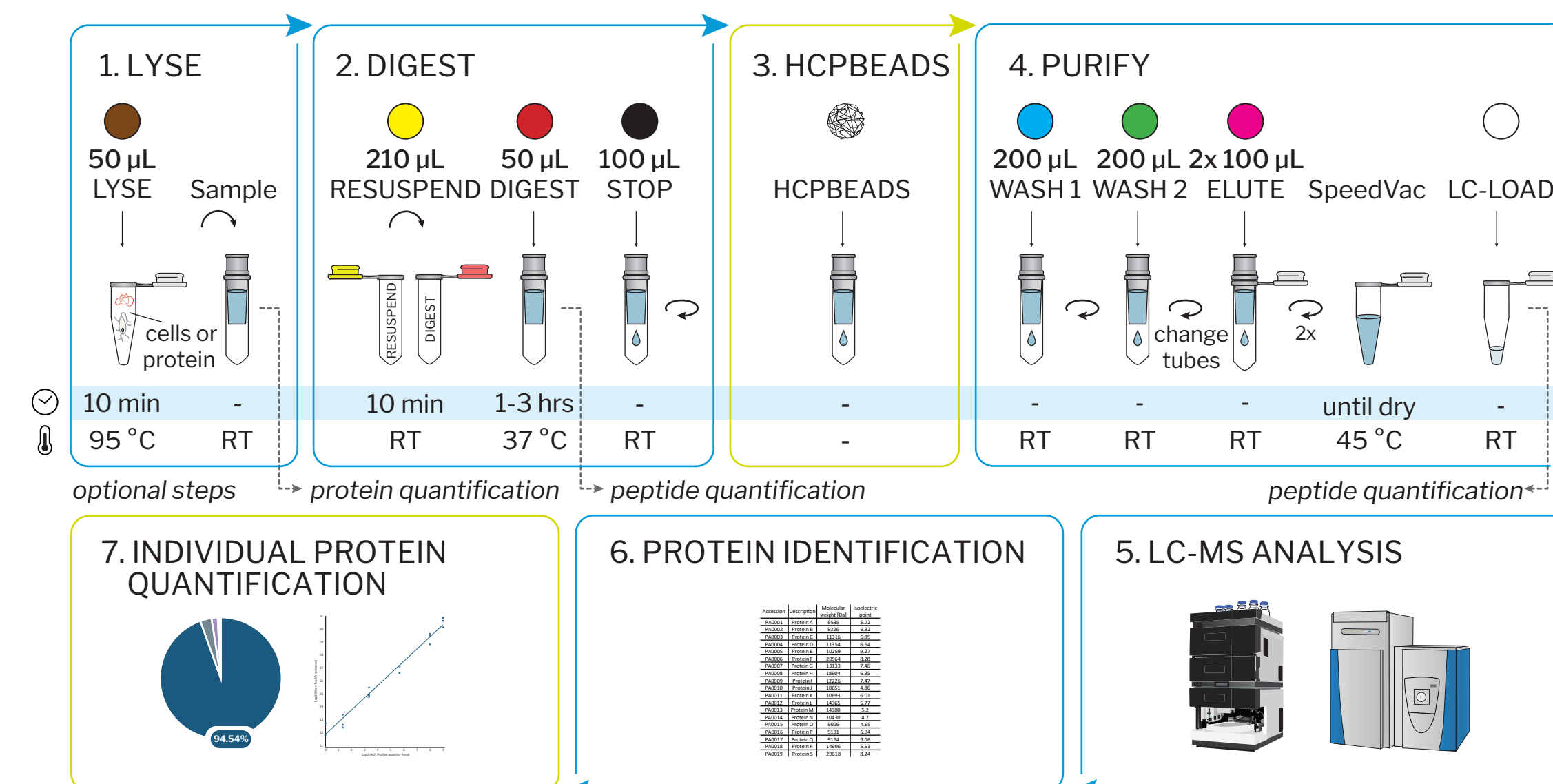
Unique workflow for individual accurate quantification and detection of host cell proteins

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Monitoring process related impurities

- Endogenous host cell proteins (HCPs) of expression organism could contaminate the biologics product despite multiple purification steps in a process
- Even traces of HCPs could affect product quality, efficacy, and patient safety
- There is a great need to identify and accurately quantify co-purifying HCPs

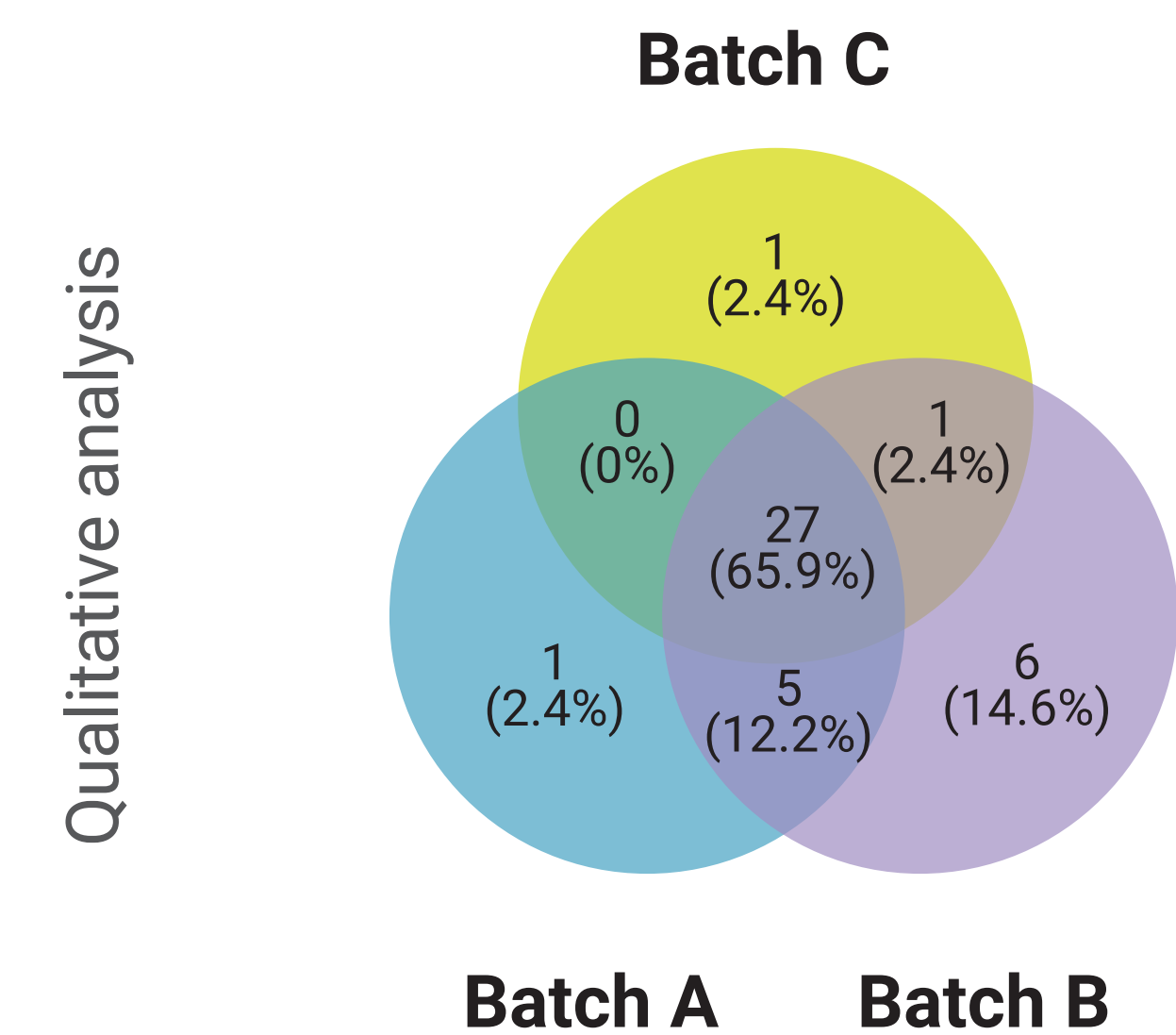
Fully standardized HCP workflow for monitoring process-related impurities



- **HCP sample:** Three batches of drug substance
- **Sample preparation:** iST-BCT kit, HCPBEADS
- **LC-MS analysis:** RSLC Ultimate 3000 nanosystem LC, Q-Exactive HF
- **Data analysis:** X!Tandem search engine, Proline for TOP3 peptides
- **Data report:** HCP-PROFILER

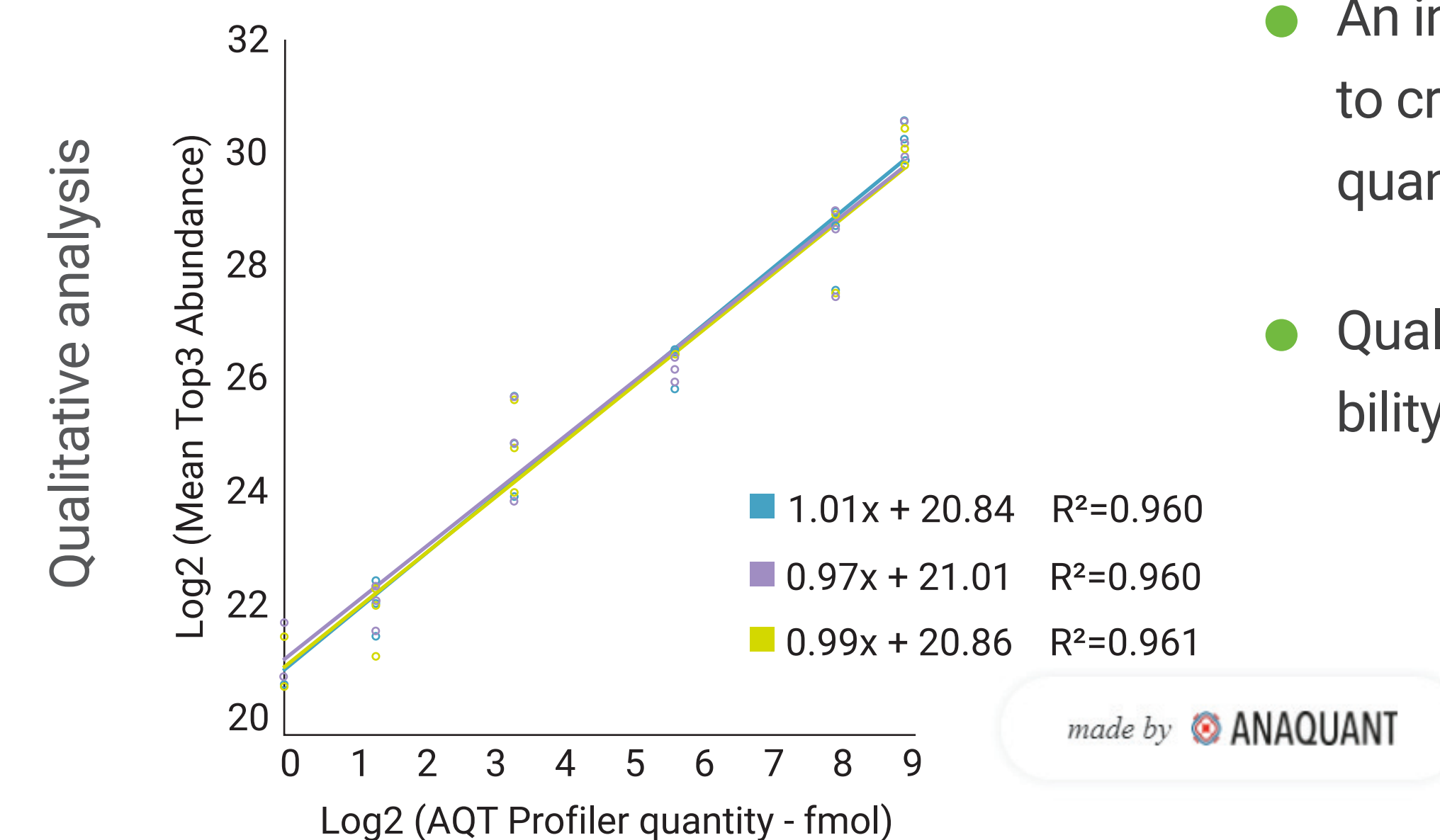
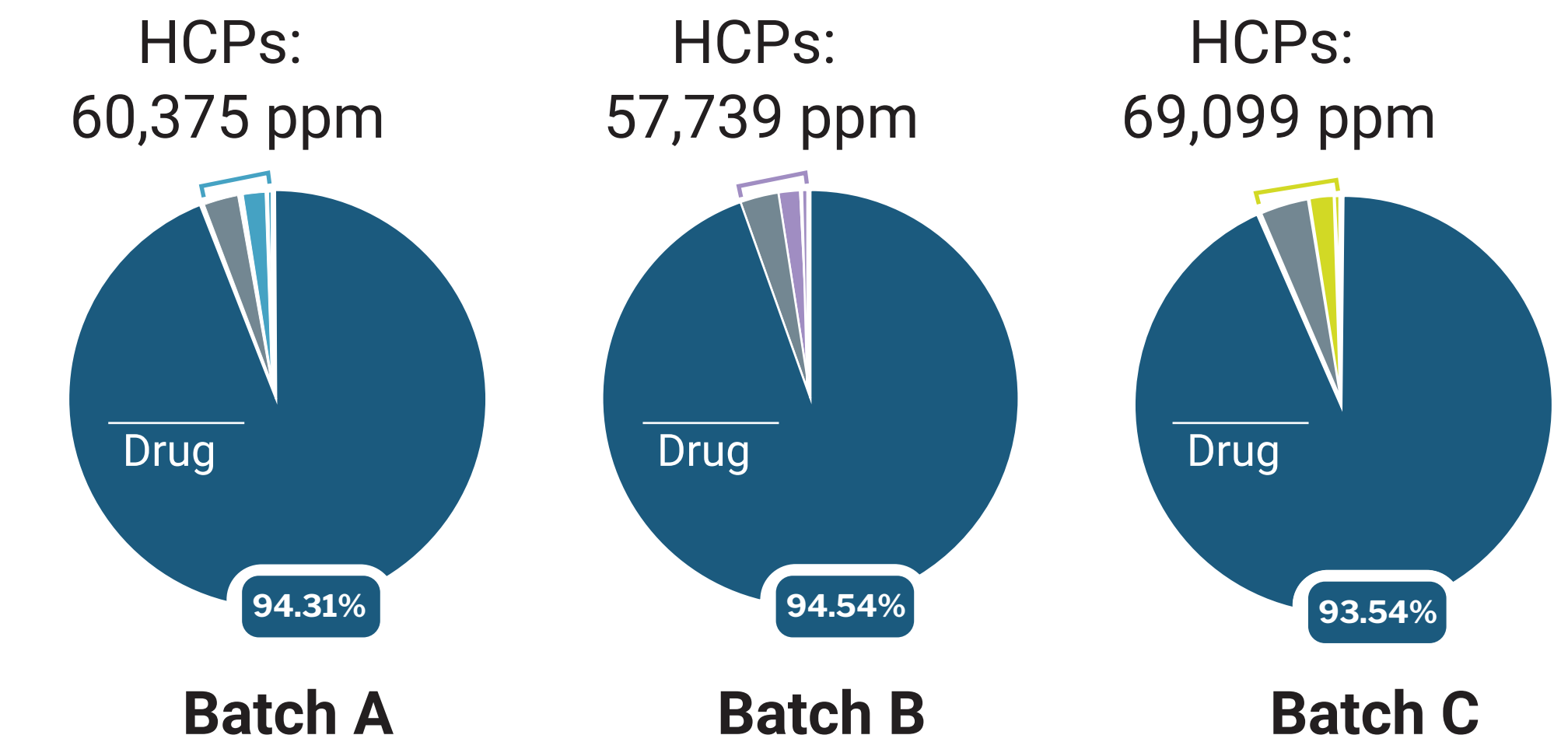
Results & Discussion

Evaluation of three batches of drug substance



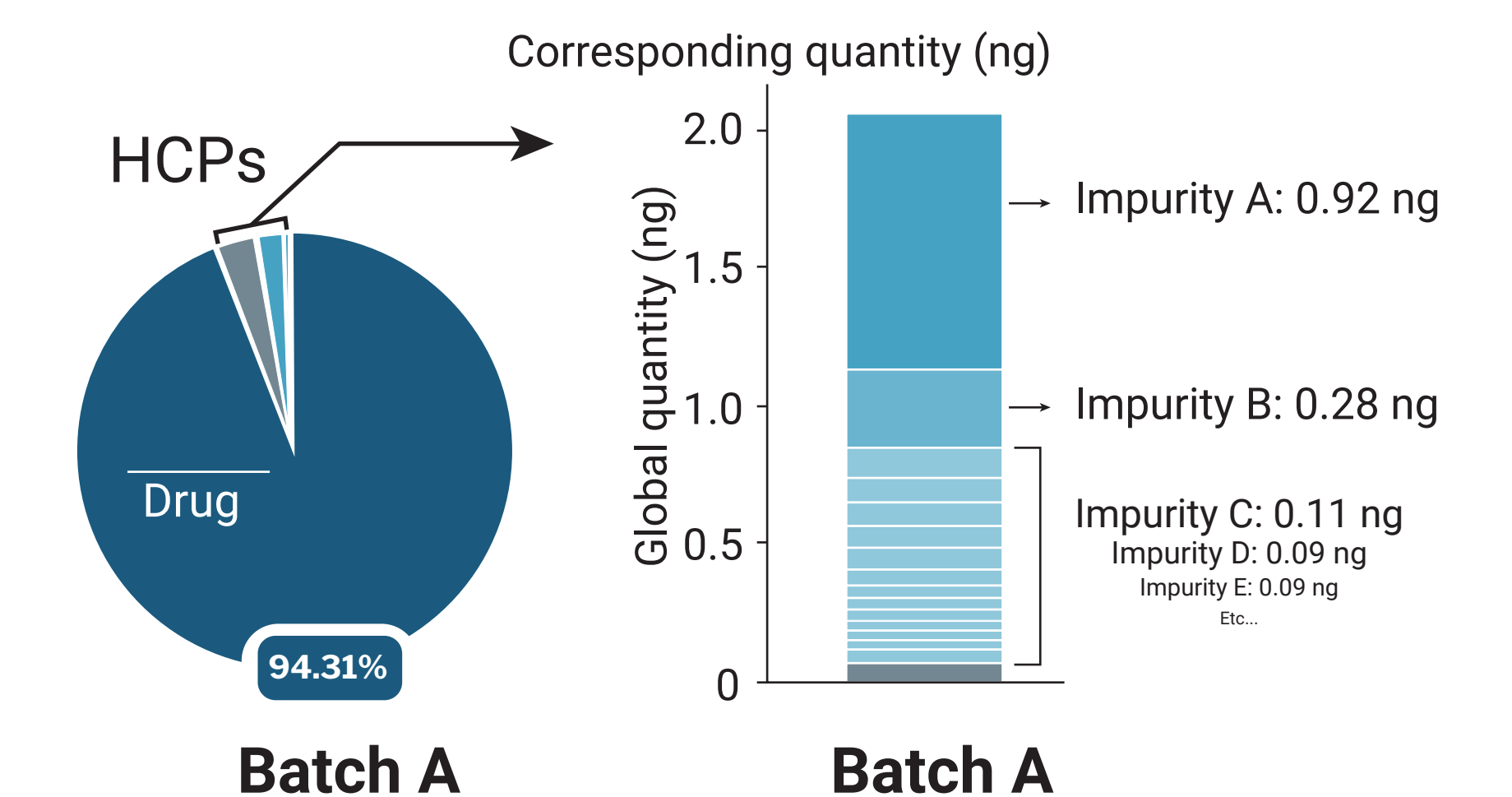
- In total 35 HCPs were identified
- Out of these, 8 HCPs were unique as a result of variation between production batches

The total quantity of co-purifying HCPs



- An internal standard of 54 peptides is used to create a calibration curve to assign the quantity of individual HCPs in the batch
- Quality control analysis shows the reproducibility of HCP workflow

Quantity of individual HCPs in batch A



Key Takeaways

- Provides a fully standardized protocol to detect impurities from the manufacturing of biotherapeutics
- Is able to identify and quantify individual process-related impurities
- Provides reproducible, accurate, and reliable quantitative data for particular impurity