Strategic Plans: Protein Analysis Working Group

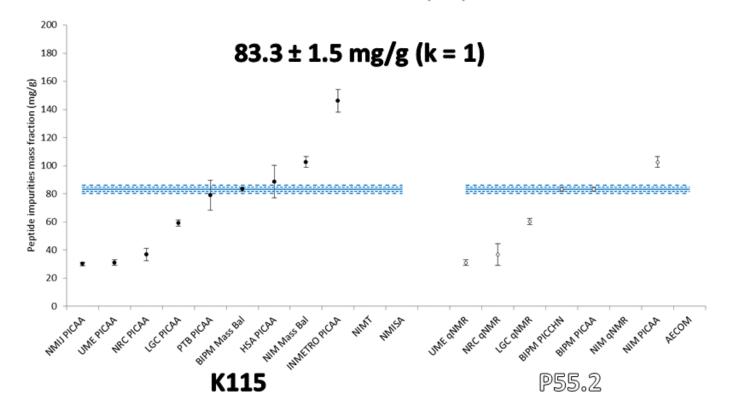
2017. 04. 26

Snag-Ryoul Park



- I. Major Achievement
 - 1. Accomplishment of K115/P55.2 study
 - Purity determination of human C- peptide

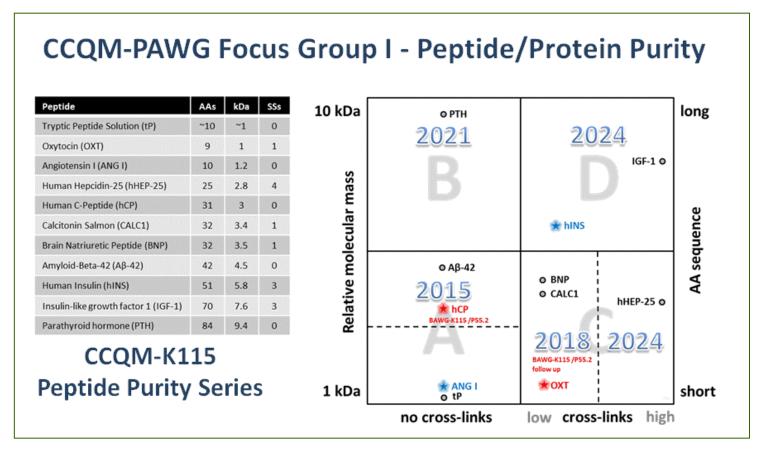
CCQM-K115 and -P55.2 – KCRV_{PepImp}



I. Major Achievement

2. Two Focus Groups Launched

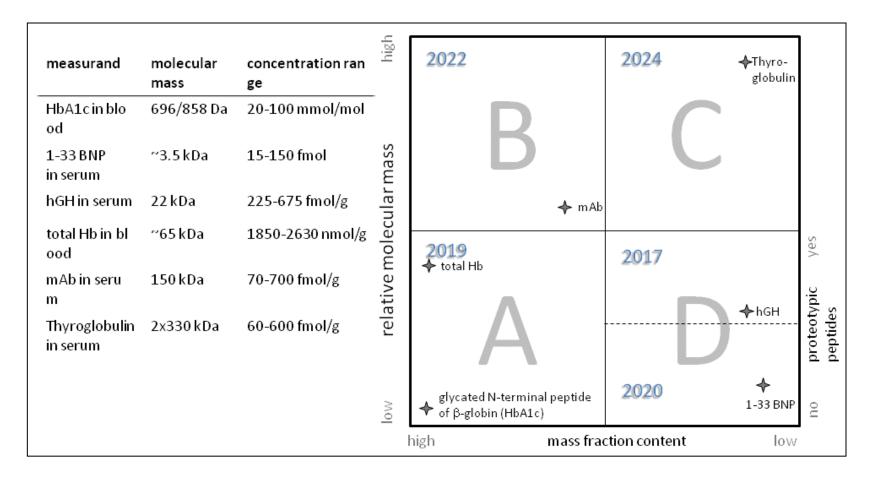
• Focus Group I: Measurement Traceability



I. Major Achievement

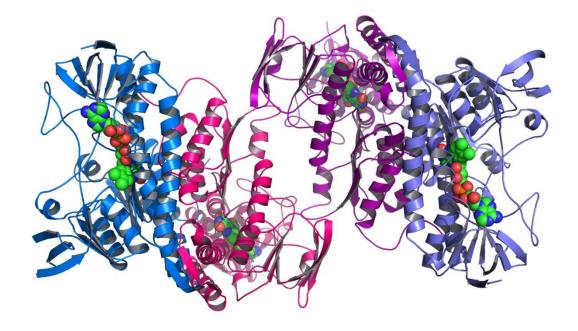
2. Two Focus Groups Launched

Focus Group 2: Measurement Capability



II. Major Challenges

- Complexity in meausrands
- Enormous work and cost to establish traceability
- Relatively large uncertainty
- Large gaps between metrology and stakeholders

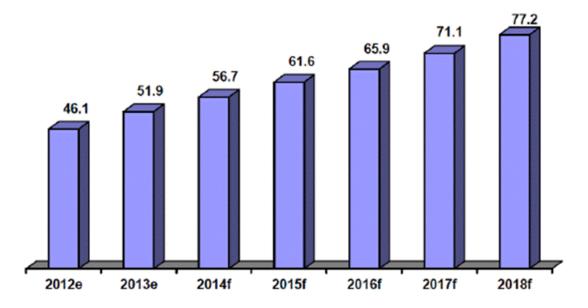


III. New in Strategy

- The 3rd Focus Group (Metrology for Protein Biologics)?
- To catch up high impact protein biologics industry

Promising growth of therapeutic antibodies

World-wide therapeutic antibodies markets (Billion US4, 2012-2018)



出典: Global Protein Therapeutics Market Outlook 2018 (RNCOS, January 2014) e:estimated, f:forecast

III. New in Strategy

- The 3rd Focus Group (Metrology for Protein Biologics)? **
- A tremendous set of analytical methods applied

Alternative version: Understanding the Critical Quality Attributes (CQA) of complex biological molecules

- Shape / higherorder structure
- Circular Dichroism (DMS)
- Fluorescence
- FTIR
- X-Ray Structure
- NMR
- Epitope Detection (HDX)
- Specific Binding
- Nmaps
- DSC

Structure / Sequence

- N- and C-terminus
- Amino Acid Analysis
- Peptide Mapping and Sequencing
- Monosaccharide Analysis
- Oligosaccharide Mapping
- Mass Spectrometry
- **Disulphide linkage**
- Assay Bioassay in vivo and in vitro OD, HPLC, AAA, Biacore, Specific binding assay ELISA, IFMA, Bradford, Lowry, Cell, based bioassay Carbohydrate analysis
 - ESI-MS (whole molecule)
 - MALDI-TOF (released carboh.)
 - Separation of labelled released carbohydrates (2-AA, 2-AB)

- Surface charge
 - IEF
 - CZE
 - IEX-HPLC
 - iCE3
 - Chromatofocusing

Size & Aggregation

- SE-HPLC (also identity and assay)
- SDS PAGE / Bioanalyser
- AUC
- AF4
- LLS

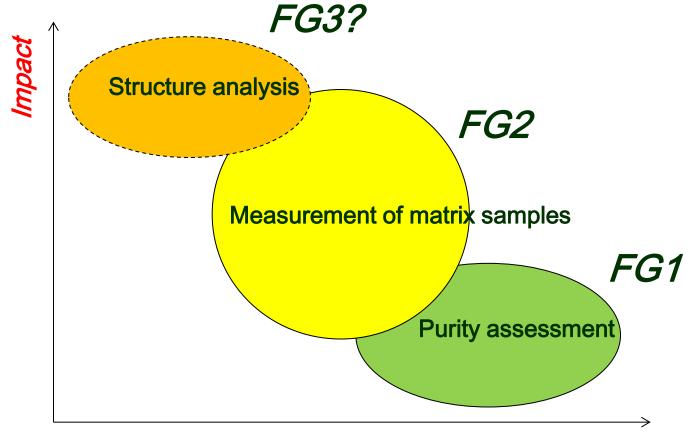
Purity

- **RP-HPLC**
- SE-HPLC
- Peptide mapping
- SDS-PAGE
- Field Flow Fractionation

- Identity
 - N-Terminal Sequence
 - Peptide Mapping
 - Specific Bioassay
 - IEF
 - HPLC

III. New in Strategy

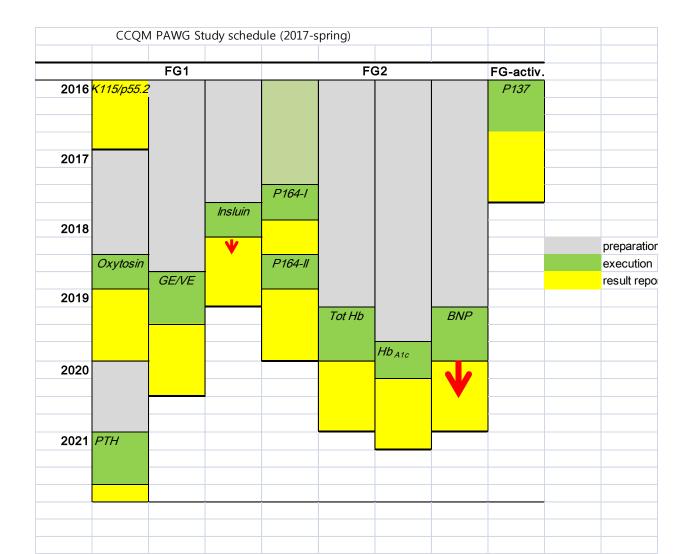
- The 3rd Focus Group (Metrology for Protein Biologics)?
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Metrological Soundness

IV. Planned comparisons

* One comparison for each focus group a year



Thank you!

KRISS