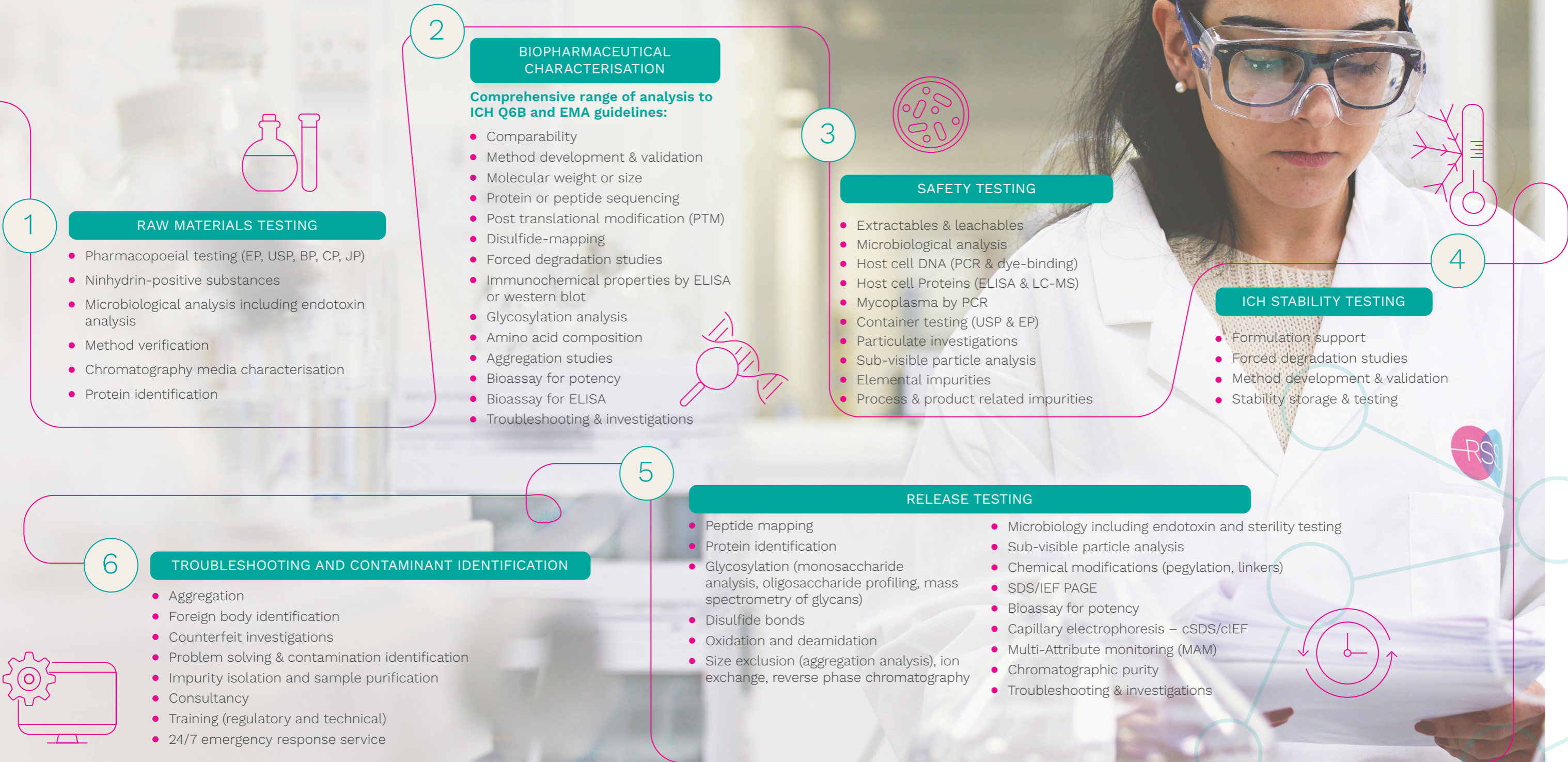


Biological Road Map – from concept to market



The success of your biopharmaceutical product is dependent on it meeting regulatory requirements for safety, efficacy and quality. Our multidisciplinary expertise and extensive portfolio of analytical methods will help you navigate your biopharmaceutical challenges beginning with:



1

RAW MATERIALS TESTING

- Pharmacopoeial testing (EP, USP, BP, CP, JP)
- Ninhydrin-positive substances
- Microbiological analysis including endotoxin analysis
- Method verification
- Chromatography media characterisation
- Protein identification

2

BIOPHARMACEUTICAL CHARACTERISATION

Comprehensive range of analysis to ICH Q6B and EMA guidelines:

- Comparability
- Method development & validation
- Molecular weight or size
- Protein or peptide sequencing
- Post translational modification (PTM)
- Disulfide-mapping
- Forced degradation studies
- Immunochemical properties by ELISA or western blot
- Glycosylation analysis
- Amino acid composition
- Aggregation studies
- Bioassay for potency
- Bioassay for ELISA
- Troubleshooting & investigations

3

SAFETY TESTING

- Extractables & leachables
- Microbiological analysis
- Host cell DNA (PCR & dye-binding)
- Host cell Proteins (ELISA & LC-MS)
- Mycoplasma by PCR
- Container testing (USP & EP)
- Particulate investigations
- Sub-visible particle analysis
- Elemental impurities
- Process & product related impurities

4

ICH STABILITY TESTING

- Formulation support
- Forced degradation studies
- Method development & validation
- Stability storage & testing

5

RELEASE TESTING

- Peptide mapping
- Protein identification
- Glycosylation (monosaccharide analysis, oligosaccharide profiling, mass spectrometry of glycans)
- Disulfide bonds
- Oxidation and deamidation
- Size exclusion (aggregation analysis), ion exchange, reverse phase chromatography
- Microbiology including endotoxin and sterility testing
- Sub-visible particle analysis
- Chemical modifications (pegylation, linkers)
- SDS/IEF PAGE
- Bioassay for potency
- Capillary electrophoresis – cSDS/cIEF
- Multi-Attribute monitoring (MAM)
- Chromatographic purity
- Troubleshooting & investigations

6

TROUBLESHOOTING AND CONTAMINANT IDENTIFICATION

- Aggregation
- Foreign body identification
- Counterfeit investigations
- Problem solving & contamination identification
- Impurity isolation and sample purification
- Consultancy
- Training (regulatory and technical)
- 24/7 emergency response service

