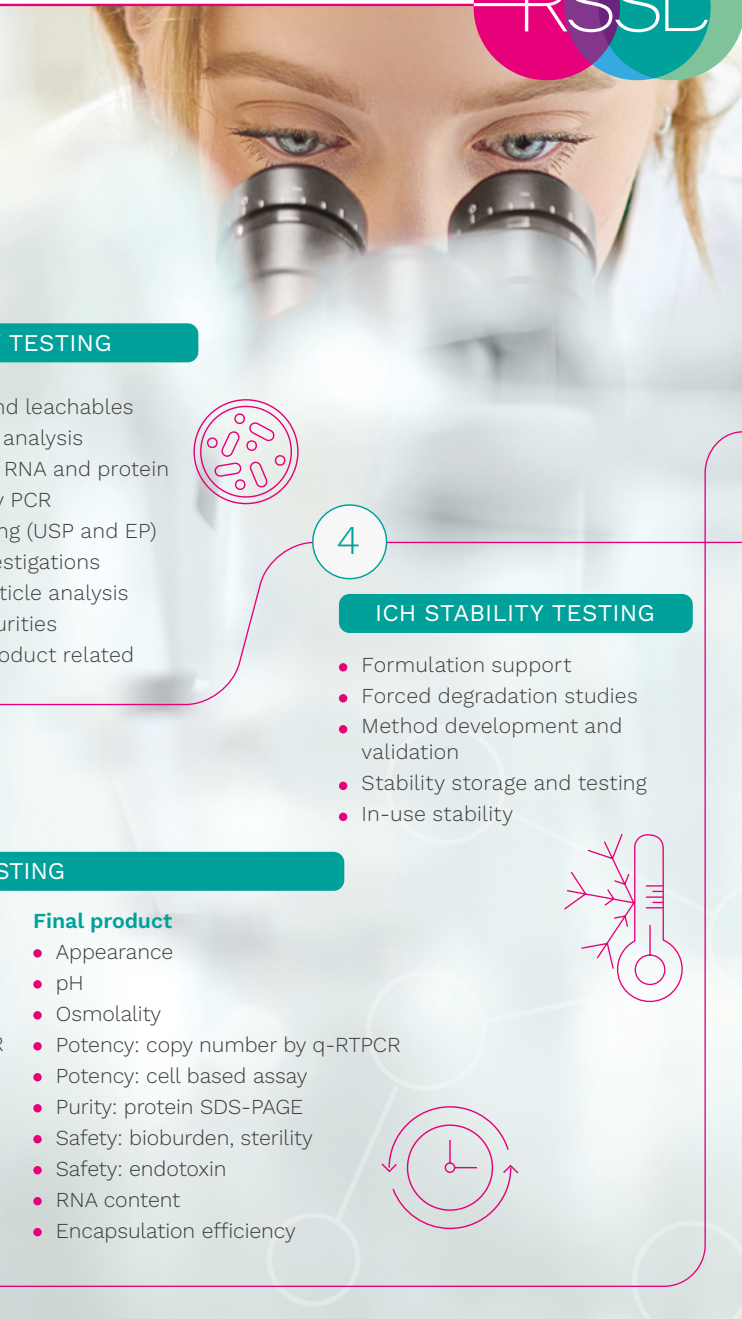


# RNA road map – from concept to market



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.



1

## RAW MATERIALS TESTING

- Pharmacopoeial testing (EP, USP, BP, CP, JP)
- Ninhydrin-positive substances
- Microbiological analysis including endotoxin analysis
- Method verification
- Chromatography media characterisation
- Biological/novel materials
- Lipids e.g. DSPC, cholesterol, cationic nucleotides



2

## CHARACTERISATION

### Capillary electrophoresis

- Purity and identity
- Quantification
- Intact RNA in viral vectors

### Mass spectrometry

- Intact mass
- Sequencing
- Impurities



### LNP delivery vehicle characterisation

- Density, viscosity
- Osmolality, glass transition temperature
- Size and charge distribution
- Encapsulation efficiency

3

## SAFETY TESTING

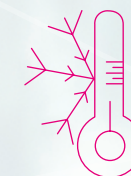
- Extractables and leachables
- Microbiological analysis
- Host cell, DNA, RNA and protein
- Mycoplasma by PCR
- Container testing (USP and EP)
- Particulate investigations
- Sub-visible particle analysis
- Elemental impurities
- Process and product related impurities



4

## ICH STABILITY TESTING

- Formulation support
- Forced degradation studies
- Method development and validation
- Stability storage and testing
- In-use stability



5

## RELEASE TESTING

### Harvest bulk drug substance

- Appearance
- Osmolality
- Potency: q-PCR product specific
- Sequence confirmation: MS/Sanger/qPCR
- RNA concentration: UV spectroscopy
- Purity: protein SDS-PAGE
- Purity: OD260/OD280
- Purity: residual host-cell DNA, RNA and protein
- Purity: other residuals e.g. BSA, caesium
- Safety: endotoxin, sterility

### Final product

- Appearance
- pH
- Osmolality
- Potency: copy number by q-RT-PCR
- Potency: cell based assay
- Purity: protein SDS-PAGE
- Safety: bioburden, sterility
- Safety: endotoxin
- RNA content
- Encapsulation efficiency



6

## TROUBLESHOOTING AND CONTAMINANT IDENTIFICATION

- Aggregation
- Foreign body identification
- Counterfeit investigations
- Problem solving and contamination identification
- Impurity isolation and sample purification
- Consultancy
- Training
- 24/7 Emergency Response Service

