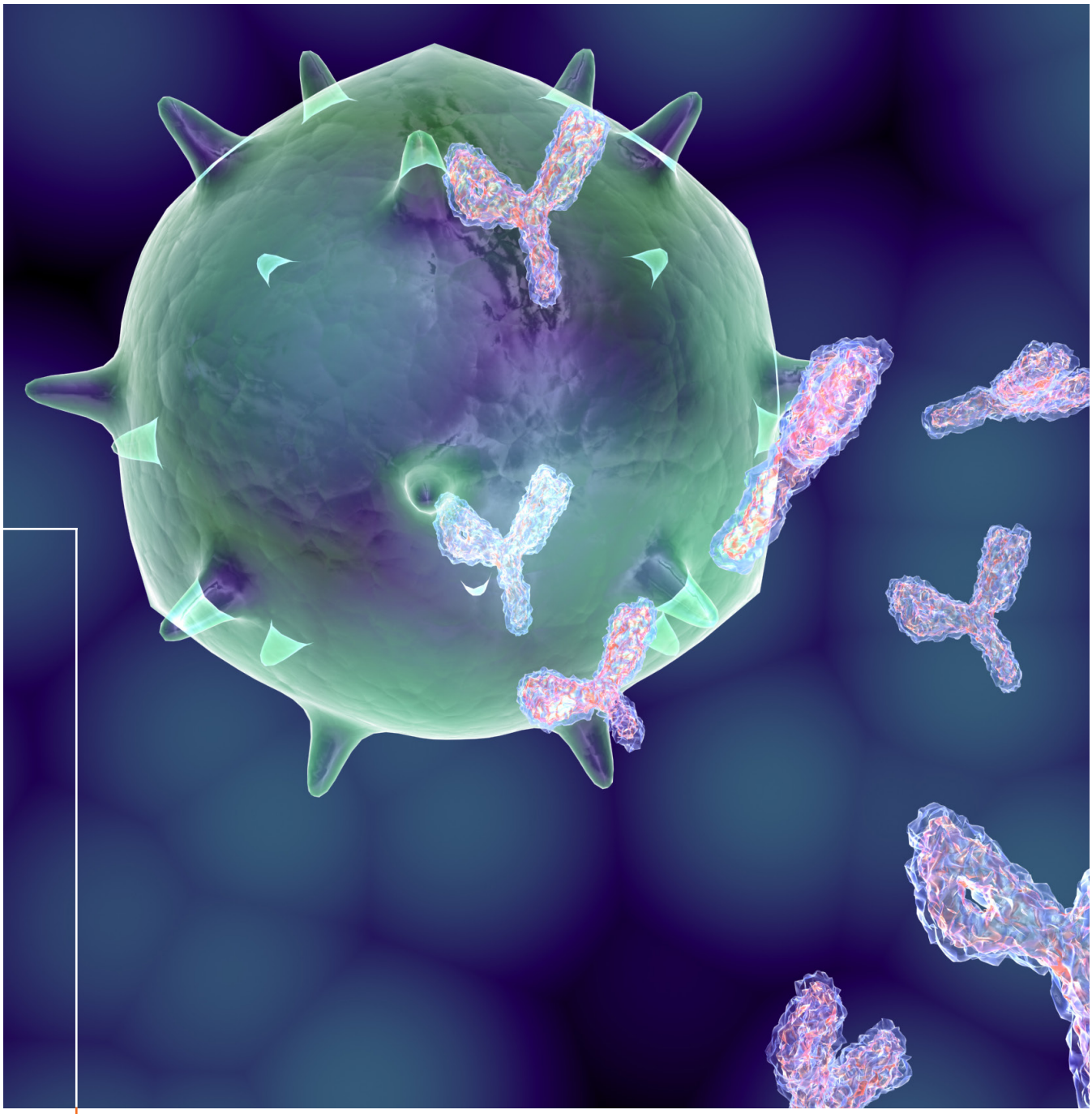


BIOPRODUCTION TESTING

SGS EXPERTISE TO SERVE INNOVATION

SGS

BIOPRODUCTION CYCLE & TESTING

BIOPRODUCTION TESTING

1. RAW MATERIAL TESTING

Raw materials have to be tested according to GMP requirement.
Our expertise covers more than 1000 products and 6000 tests performed via chemical or microbiological techniques described on Pharmacopeias (BSA, container closure interaction, excipients...).
Chemical testing requires instrumental techniques such as separative (HPLC, GC...), spectrophotometric (SAA, ICP...), and wet chemistry equipments (FTIR, UV...).

Microbiological testing is focused on :

- Sterility testing, EP 2.6.1, USP <71>
- Endotoxin detection, EP 2.6.14, USP <85>
- Detection, identification and quantification of microbial contamination (bioburden, EP 2.6.12 & 2.6.13, USP <61> & <62>
- Mycoplasma detection, EP 2.6.7 & USP <63>

Our long term expertise on raw material testing also applies to qualification of bioproducts which are not described in Pharmacopeias such as buffers, cell culture media...by amino acid, vitamin and ionic profiles.

2. IDENTITY

MOLECULAR STRUCTURE

Drug product or drug substance identity is confirmed by :

- Aminoacid composition with aminoacid analyzer, EP 2.2.56, USP <1052>
- Peptid mapping by cIEF, EP 2.2.55
- Heterogeneity profile by HPLC
- N-terminal sequences analyses and carbohydrate structure (glycosylation) by SEC-HPLC or EC

PHYSICO-CHEMICAL PROPERTIES

Drug product identity is also confirmed by determination of physicochemical properties :

- Molecular weight and size by SEC-HPLC, SDS-PAGE, CE-SDS, and Western blot
- Isoform patterns by cIEF
- Liquid chromatographic patterns

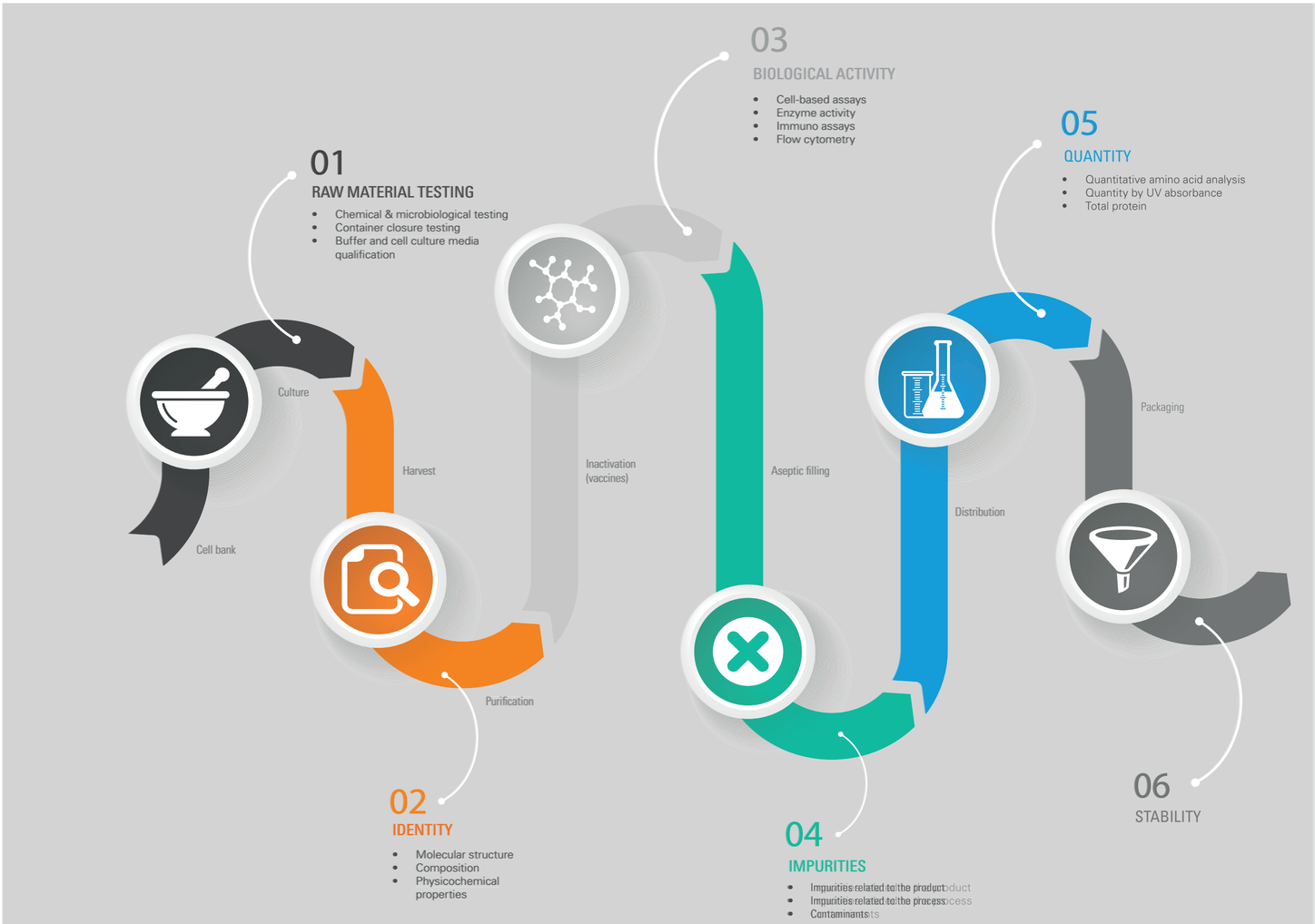
3. BIOLOGICAL ACTIVITY

POTENCY ASSAY

- Cell based assay
- Binding assay
- Enzyme activity
- Immunoassays

OTHER TESTS

- Flow cytometry (FACS)
- Western Blot



BIOPRODUCTION TESTING

4. IMPURITIES

RELATED TO THE PROCESS

Cell substrate impurities

- HCP quantification by ELISA, EP 2.6.34, USP <1132>
- Residual DNA quantification by ELISA or qPCR USP <1130>

Cell culture derived impurities such as inducers, antibiotics, serum and other media components can be detected by chromatography.

Finally, **downstream derived impurities** as enzymes, inorganic salts, leachables, elemental impurities, ligands or solvents can be analyzed by chromatography or ICP/MS.

RELATED TO THE PRODUCT

- Truncated forms by SEC-HPLC or SDS Page
- Aggregates by SEC-HPLC or capillary electrophoresis
- Other modified forms : deamidation, dimers, oxydation, glycosylation, phosphorylation, conjugated forms...by HPLC or capillary electrophoresis.

CONTAMINANTS

- Sterility testing, EP 2.6.1, USP <71>
- Endotoxins detection, EP 2.6.14, USP <85>
- Mycoplasma detection by culture, fluorescence (Vero indicator cell line) and qPCR, EP 2.6.7 & USP <63>
- Detection, identification and quantification of microbial contamination (bioburden), EP 2.6.12 & 2.6.13, USP <61> & <62>
- Virus detection EP 2.6.16, ICH Q5A(R1)

5. QUANTITY

- UV absorbance at 280 nm (using extinction coefficient)
- Total protein C/H/O/N determination, EP 2.5.33
- Quantitative amino acid analysis, EP 2.2.56 & USP <1052>
- Relative potency assay

6. STABILITY

Drug Substance and Drug Product stabilities studies are performed according to ICH guidelines :
ICH Q1A (R2) & ICH Q5C

STABILITY STORAGE CAPACITIES

Climatic chambers
- 25°C / 60%
- 30°C / 65%
- 30°C / 75%
- 40°C / 75%
- 30°C / 35%
- 25°C / 40%
- 40°C / 25%

Coolers & freezers
- +5°C ; -20C° ; -80C°

BIOPRODUCTION TESTING
SGS EXPERTISE TO SERVE INNOVATION

Using the capacities of living organisms (tissues, cells, proteins ...) or parts of them (genes, enzymes, etc.), biotechnologies have radically changed the way in which drugs are produced.

SGS innovates to support its clients in their transition and growth in bioproduction.
Whatever your activity in the pharmaceutical, biotechnology or veterinary sector; whether you are in big pharma, start-up or academic; your bioproducts (monoclonal antibodies, therapeutic cells, vaccines, recombinant proteins, ADCs, etc) are becoming increasingly challenged throughout the stages of the biomolecule production process.

To ensure the quality and safety of the bio drug, the ICH Q6B and Pharmacopeia guidelines specify the controls to be carried out throughout the bio-product manufacturing cycle.

SGS laboratories support you in this process by verifying the identity and activity of a biomolecule, the nature of impurities linked to processes or products, the stability of the product, and control of the raw materials involved in the bioprocess.
We put at your service our knowledge and mastery of Quality and Good Manufacturing Practices and our technical abilities to advise and assist you in your approach to quality control of biomedicines.

SGS laboratories are investing to provide you with a dedicated structure and a team of experts able to adapt to the new challenges posed by bioproducts.

CONTACT US

SGS FRANCE
LIFE SERVICES DIVISION

4, rue du Commandant d'Estienne d'Orves
92390 Villeneuve-la-Garenne
FRANCE

t. + 33 (0) 1 41 06 95 85
f. + 33 (0) 1 41 06 95 98

fr.pharmaqc2@sgs.com
www.sgsgroup.fr

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.

* SGS Villeneuve-La-Garenne one expert laboratory to ensure quality of your bioproducts

N°420 OCTOBER 2018

WWW.SGS.COM
WWW.SGSGROUP.FR

WHEN YOU NEED TO BE SURE

SGS