

Eurofins Biopharma Product Testing :

Focus sur les nouvelles capacités analytiques et de logistique clinique 2015



BioPharma
Product Testing



Chemical & Biochemical analysis

HPLC, GC, MS, spectrophotometry, ICP, ELISA, SDS PAGE



Microbiological tests

Organism identification, sterility testing, bioburden, endotoxin, mycoplasma



Bioassay & biosafety

Potency assay, residual DNA



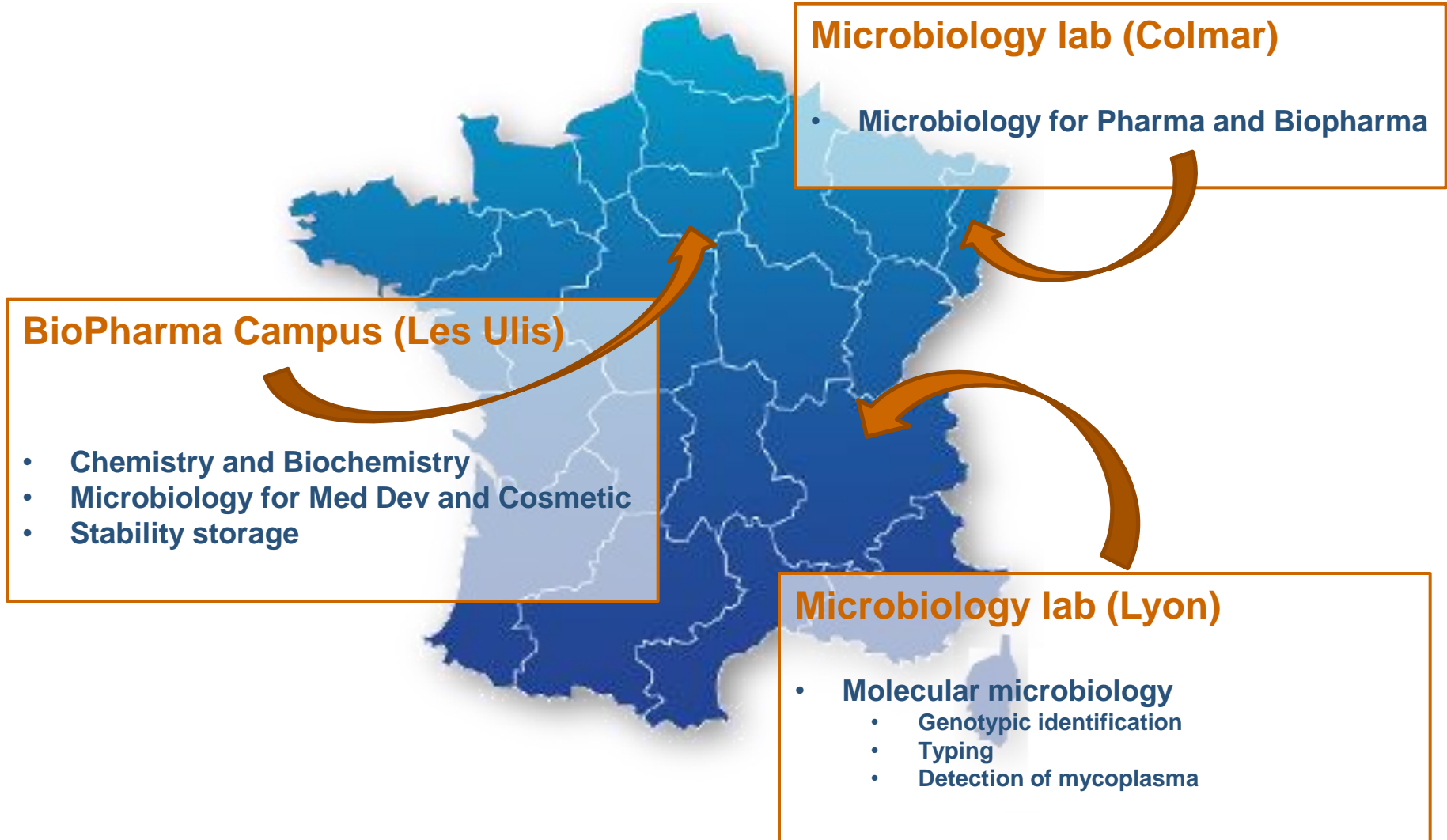
Cell banking & storage

Preparation of master and working cell banks (US)



Clinical Supply

Batch importation & release, clinical manufacturing, storage and distribution



New Building in operation :

- **3,000 m² with 2,325 m³ of ICH storage**
- **Doubling our current capacity on ICH studies**
- **Storage of cells (liq. N2)**
- **Climatic room dedicated as back-up chamber for customer's Disaster Recovery Plan**



New capacities in logistic 2015 & 2016

■ Several chambers including the following conditions:

25°C ± 2°C/60% RH ± 5% RH	287 m ³
25°C ± 2°C/40% RH ± 5% RH	108 m ³
30°C ± 2°C/35% RH ± 5% RH	40 m ³
30°C ± 2°C/65% RH ± 5% RH	103 m ³
30°C ± 2°C/75% RH ± 5% RH	111 m ³
40°C ± 2°C/75% RH ± 5% RH	82 m ³
40°C ± 2°C/ (NMT) 25% RH	42 m ³
Customized (x3)	3 m ³
20°C ± 5°C	505 m ³
5°C ± 3°C	960 m ³
- 20°C ± 5°C	80 m ³
- 80°C ± 5°C	6 m ³
Cycling (-100°->90°C; 25->90 %HR)	1.2 m ³
Photostability (regulation on lux and temperature)	0.3 m ³
SCAD5 (monitoring system for humidity, temperature and alarm)	1



Clinical storage, packaging & logistic :

- **Storage of samples & kits**
- **Clinical labelling**
- **Secondary packaging : kit design & assembly**
- **Global clinical logistic : controlled temperature transport**
- **Return & destruction**



Microbiology testing

- Revamping of 300 m² zone dedicated to microbiology testing
- Non-sterile product
- Antibiotic testing

Extension of chemistry / biochemistry lab :

- Investment in iCE and CE
- Major investment in HPLC/UPLC system
- Creation of an additional 400 m² GMP lab in 2016
- Refurbishment of current HPLC and Wet Chemistry lab



New lab acquisition Sinensis Life Sciences (NL) in January 2016 :

- Biosafety testing : virus assays, cell line authentication, purity tests
- Fill & finish services

