

# QUALITY SAFETY ENVIRONMENT MANUAL



# SPECIALIZED MEDICAL BIOLOGY

Founded in 1967, the Cerba laboratory is a **reference** in speciality medical biology. For over 50 years, it has been providing patients and healthcare professionals with a wide range of medical expertise and a unique medical biology range, combined with a strong capacity for innovation.


## Tests

- **Complex tests** (hormonology, virology, toxicology, haemostasis, allergology, mycobacteriology, autoimmunity, etc.)
- **Cytogenetics** (prenatal/post-natal, oncohaematology)
- **Molecular genetics** (PCR / sequencing, etc.)

## Customers

- **Private medical analysis laboratories**
- **Public and private health establishments**
- **Doctors, midwives**
- **Public institutions** (screening campaigns)

## Location

- **Frépillon**, a single site bringing together all the expertise and serving more than 50 countries
- **Cofrac accreditation ISO 15 189 N°08-0945**  **available on [WWW.cofrac.fr](http://WWW.cofrac.fr)**

# NOS VALEURS

## EXIGENCE

We work with the greatest rigour to improve the quality of our services, and develop the men and women in the company to get the best from each of them for the benefit of all.

## COMMITMENT

Our commitment to doctors, patients and our industrial and institutional partners is to deliver results that are both accurate and useful in improving the health of everyone.

## AUDACE

We promote an entrepreneurial spirit and encourage initiative in all our activities, so that we can dare to explore new ways of advancing diagnosis.

## RESPECT

We treat each individual with kindness and cultivate respect in our relationships with our teams, partners, healthcare professionals and patients, for whom we work on a daily basis.

# OUR QUALITY POLICY

For several years, the Cerba laboratory has occupied a central position in medical biology, remaining committed to its values of high standards, commitment, respect and audacity. These values illustrate the laboratory's desire to position itself in a committed and human perspective of medical biology, at the heart of our patients' care.

Respect for the patient is of prime importance to us. Our activities are carried out impartially and in compliance with the requirements of confidentiality and medical confidentiality. We develop and implement a management system to maintain the quality of our services and guarantee the medical service rendered. We drive continuous improvement in our services, integrating the risks and opportunities of change.

The satisfaction of our patients, prescribers and all our correspondents, staff and partners is the laboratory's priority today, in an environment of constant technological and regulatory change.

As proof of its competence, reliability, reproducibility and the robustness of its results, the laboratory is accredited by the Comité français d'accréditation (Cofrac) Santé Humaine to standard NF EN ISO 15189 (N° 8-0945, Medical examinations). Scope available on [www.cofrac.fr](http://www.cofrac.fr).

Our ongoing objectives focus on 3 main areas :

- The trust of our patients, prescribers, partners and correspondents;
- Efficiency through the quality of our services and examinations, and the safety of our patients and staff;
- The coherence of our activities through the harmonisation of practices within our various units and by ensuring that our practices are in line with technological and medical developments.

To achieve these objectives, Management is committed to :

- Putting in place the necessary tools and resources;
- Promoting, implementing, monitoring and continuously improving the management system in accordance with the regulatory requirements and standards applicable to our various activities, and in particular the requirements of standard NF EN ISO 15189, as well as Cofrac's binding documents;
- Compliance with good professional practice;
- Maintaining the necessary skills by training our staff and partners, managing careers and making our working conditions and values attractive;
- Guaranteeing the protection of patients' and employees' personal data;
- Deploying our Corporate Social Responsibility policy.





**Aware that quality can only be part of a global process and that everyone is involved, we want our employees to apply quality policies and procedures, to take ownership of the quality system and to get involved in managing and achieving quality objectives.**

We would like to thank all our teams for their constant efforts.

# OUR CSR POLICY - OUR COMMITMENTS

At Cerba , we see corporate social responsibility as inherent in our commitment to advancing health and patient care. In line with our core business, CSR also involves human capital, business ethics and respect for the environment.

[Read our Extra-Financial Performance Statement](#)

THEMATICS	RISK	CSR CHALLENGE
 <b>CONTRIBUTING TO THE HEALTH OF ALL</b>	Poor quality of medical services and customer/patient relations	<b>1 Guaranteeing high-quality medical diagnosis</b>
	Risk of not covering all pathologies	<b>2 An innovative approach to provide solutions for rare or new diseases</b>
	Risk of lack of access to care	<b>3 Extending our coverage, opening up new international markets and conducting clinical trials to help develop new therapeutic solutions or vaccines</b>
	Risk of not ensuring continuity of access to care	<b>4 Guarantee continuity of the laboratory's activity and ensure that examination turnaround times meet expectations</b>
 <b>DEVELOP HUMAN CAPITAL</b>	Skills risk	<b>5 Developing skills and talent</b>
	Health/safety and QWL risks	<b>6 Safeguarding employee health and safety and improving QWL</b>
	Risk to employee attractiveness and loyalty	<b>7 Attracting and retaining staff</b>
 <b>REDUCING THE IMPACT OF OUR BUSINESS ON THE ENVIRONMENT</b>	Risk of pollution from the use of chemicals	<b>8 Reducing pollution</b>
	Risk of climate impact	<b>9 Protecting the climate</b>
	Risk of environmental impact through waste production.	<b>10 Reducing and recycling waste</b>
 <b>TO BE EXEMPLARY IN OUR BUSINESS ETHICS</b>	Disclosure/harvesting of our customers'/patients' personal data	<b>11 Protecting the personal data of patients and employees</b>
	Risk of corruption	<b>12 Preventing the risks of corruption</b>
	Health, safety and environmental risks within the activities of third parties (e.g. subcontractors, suppliers)	<b>13 Developing a responsible purchasing policy</b>

# OUR DATA PROTECTION POLICY

Cerba, a medical biology laboratory, is responsible for the personal data of its patients, employees of its partners (suppliers or customers) and applicants.

We undertake to comply with the applicable regulations for all processing of personal data that we carry out. We therefore undertake to comply with the following principles :

We process your personal data lawfully, fairly and transparently. We collect your personal data for specific, explicit and legitimate purposes and do not process it in a way incompatible with those purposes. We ensure that personal data is adequate, relevant and limited to what is necessary for the purposes for which it is processed. We make every effort to ensure that personal data is accurate and, where necessary, kept up to date. We take all reasonable steps to ensure that personal data which is inaccurate, having regard to the purposes for which it is processed, is deleted or rectified without delay. We will keep your personal data in a form that allows you to be identified only for as long as is necessary for the purposes for which it is to be processed. We guarantee an appropriate level of security for the personal data we process.

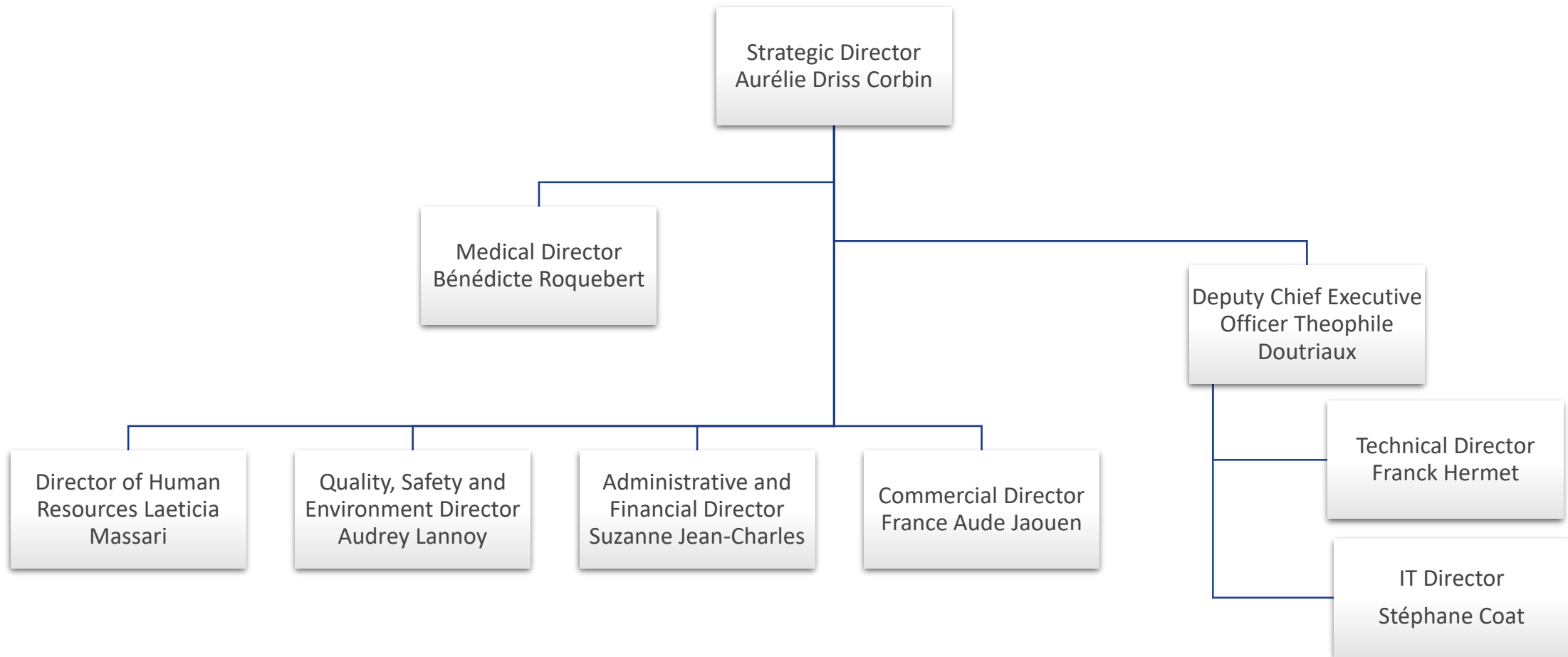
[Consult our data protection policy](#)

The Cerba laboratory participates in research projects, each of which is organised under the responsibility of a research manager/promoter. The aim of these projects is to advance scientific and medical knowledge in order, in particular, to improve treatment conditions and the quality of diagnosis and care.

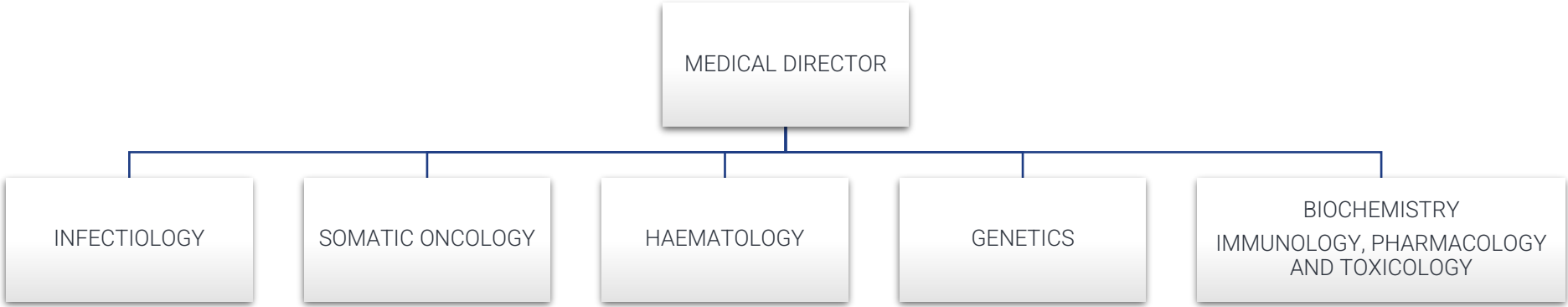
A list of each of the projects in which the Cerba laboratory is likely to participate is available on the website. For each project, it also specifies the identity of the person responsible for the research/promoter, the inclusion criteria and the categories of data processed.

[See our research projects](#)

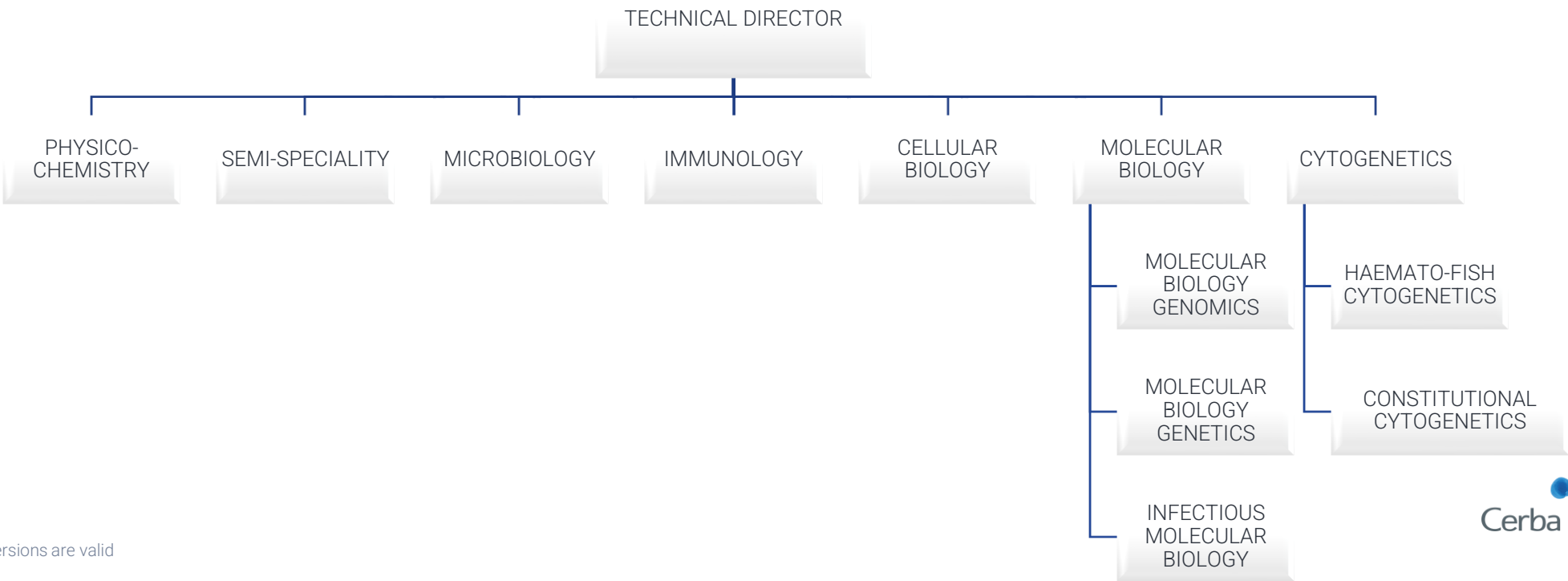
# MANAGEMENT COMMITTEE ORGANISATION CHART



# MEDICAL ORGANISATION

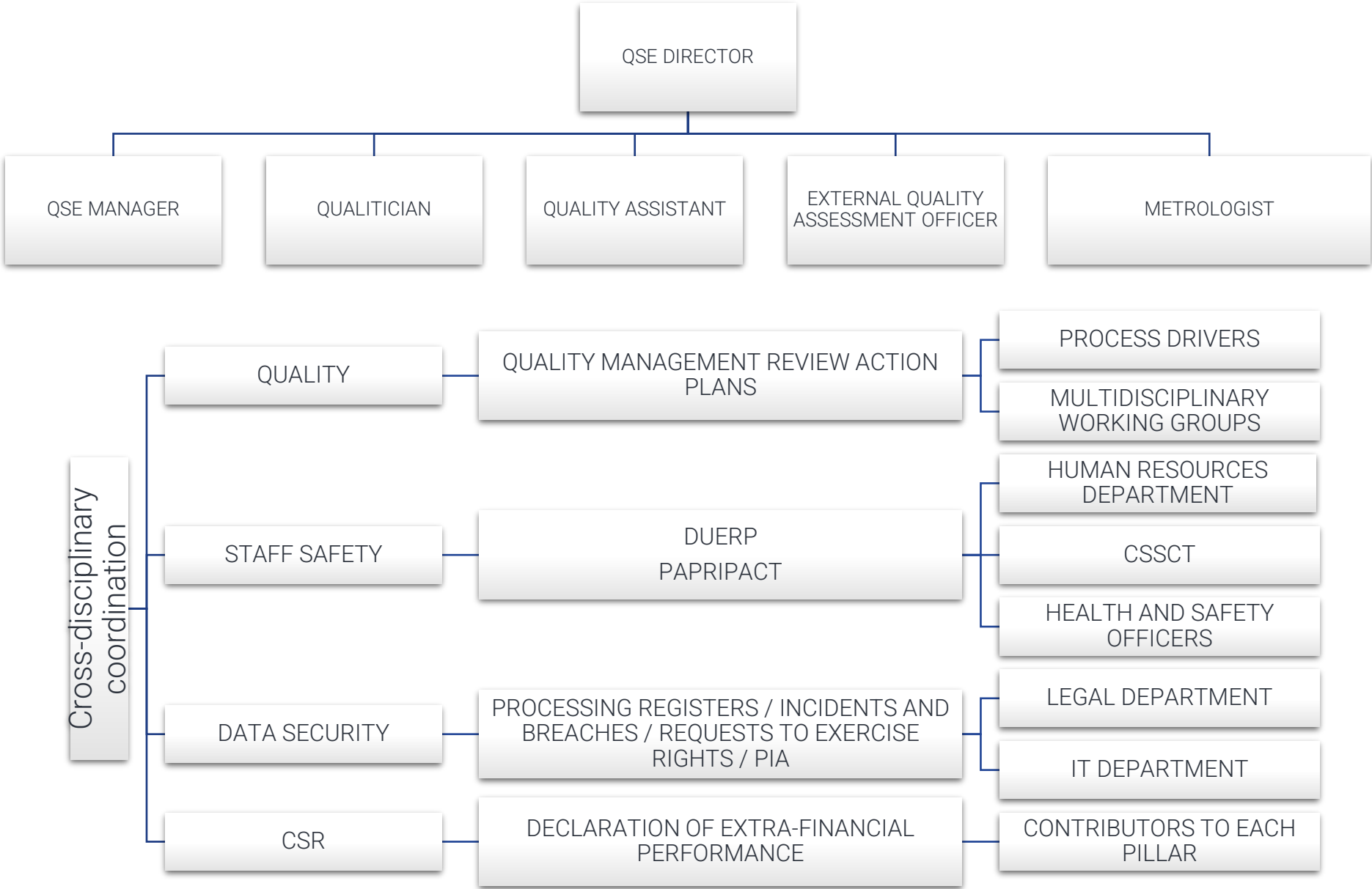


# ORGANISATION OF TECHNICAL UNITS





# QSE ORGANISATION





# Laboratory process mapping

CT-MGL-002-01

## 1 – Managing the laboratory

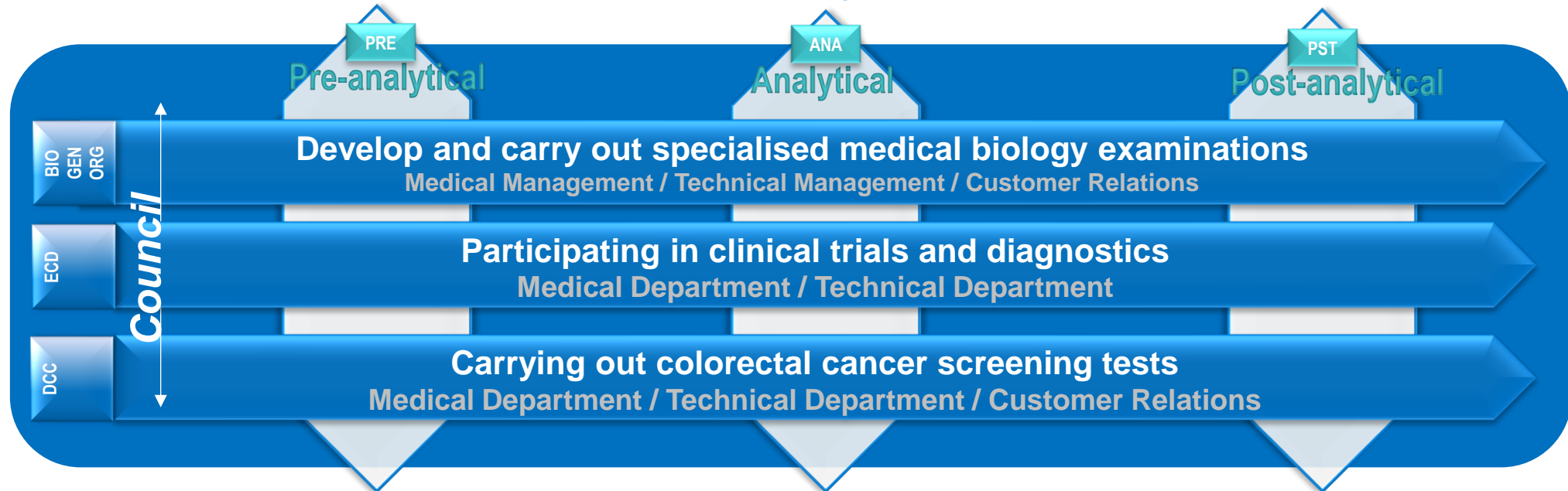
MANAGEMENT



## 2 – Controlling production

CUSTOMER NEEDS

REALISATION



CUSTOMER SATISFACTION

## 3 – Supporting business

RESOURCES



10/16

# OUR MAIN SOFTWARE

## Production

- SIL : Open Labs
- Middleware : Valdeb
- CIQ management : TQC
- Stock management: Easy Buy

## Quality

- Kalilab : Quality Management System
- SEEQ : External quality assessments
- ACIRA : Measurement uncertainties
- Auto-DV : Method validation reports
- Temperature monitoring : JRI

## IT services and maintenance

- GLPI

## Indicators

- Power BI

## Personnel management

- Overtime
- My HR

# OPERATION WITH TRANSMITTING LABORATORIES

An Operating Charter sets out in particular :

- the conditions under which the Transmitting Laboratory carries out the pre-analytical phase,
- the conditions of the organisation adopted for taking charge of the samples for analysis by the CERBA Laboratory,
- how the results will be communicated,
- how critical results are managed,
- the terms and conditions of the consultancy services provided by Laboratoire CERBA.

## QUALITY COMMITMENTS

- Laboratoire CERBA is accredited by COFRAC in accordance with standard NF EN ISO 15189 (n°8-0945, Medical Examinations). The scopes of accreditation for Laboratoire CERBA are available on the COFRAC website [[www.cofrac.fr](http://www.cofrac.fr)]. The detailed list is also available on the CERBA Laboratory website [[www.lab-cerba.com](http://www.lab-cerba.com) > « About us » > « Our quality commitments » > « Accréditations »].
- The CERBA Laboratory Quality Manual is also available on its website [[www.lab-cerba.com](http://www.lab-cerba.com) / « About us » > « Our quality commitments » > « Quality manual »].
- The Transmitting Laboratory can send all its Quality questions to the CERBA Laboratory via the tab on its site provided for this purpose. [[www.lab-cerba.com](http://www.lab-cerba.com) > « Contact us »]. This means of communication enables Laboratoire CERBA to respond as quickly as possible by e-mail to any precise and specific question relating to Quality.
- *In accordance with GEN REF 11, our clients are not authorised to use our accreditation mark (reproduction of our report is not considered as use of the accreditation mark).*

## STRUCTURAL COMMITMENTS

- The CERBA Laboratory undertakes to use a sufficient number of staff to satisfy all the pre-analytical, analytical and post-analytical phases. The CERBA Laboratory undertakes to ensure that the members of its staff have undergone the necessary training and, where applicable, have obtained the required authorisations or approvals.
- The CERBA Laboratory and the Transmitting Laboratory mutually undertake to comply with the Identity Vigilance Rules (RNIV).
- The CERBA Laboratory provides the Transmitting Laboratory with the equipment necessary for taking and transporting samples. This equipment can be ordered on its website [[www.mycerba.com](http://www.mycerba.com)].
- The test results by name are kept for a period of 10 years.
- Genetic analysis reports and their explanatory comments are kept in accordance with article R. 1131-13 for a period of thirty years.
- Once the tests have been carried out, the samples are stored in accordance with the provisions of the NABM.

# OPERATION WITH TRANSMITTING LABORATORIES

## TECHNICAL COMMITMENTS

- The CERBA Laboratory undertakes to carry out with all due care and diligence the Examinations entrusted to it by the Transmitting Laboratory.
- The expected date of delivery of the results is indicated for each file and for each Examination on the results server.
- When, in particular in cases of force majeure, the CERBA Laboratory cannot itself perform the acts entrusted to it listed in the Catalogue, it may entrust the performance thereof to another laboratory designated in advance. In this case, and when the samples submitted for biological examinations have already been received by the CERBA Laboratory, their transmission to the designated laboratory shall be carried out under its responsibility. Once the Examination has been carried out, the CERBA Laboratory stores the samples for the period stipulated by the regulations, or if the regulations do not stipulate a storage period, for a minimum of 2 weeks at the appropriate temperatures.
- Laboratoire CERBA's business continuity plan is implemented in all its departments. The organisation covered by this plan enables all medical emergencies to be dealt with as a priority thanks to :
  - Securing the building (access control, video surveillance, fire protection, duplicated power supplies and IT networks, generator)
  - Deployment of automated systems or back-up techniques;
  - The implementation of a 'gold' contract policy with the CERBA Laboratory's suppliers with 'short' lead times for dealing with breakdowns;
  - Setting up occasional subcontracting, if necessary

# OPERATION WITH TRANSMITTING LABORATORIES

## MEDICAL COMMITMENTS

- Laboratoire Cerba holds the following authorisations for healthcare activities subject to approval:
  - Pre-natal diagnosis activities (DPNI)
  - Post-natal diagnostic activities: examination of a person's genetic characteristics or identification of a person by genetic fingerprinting for medical purposes.
- The CERBA Laboratory undertakes to communicate the results to the Transmitting Laboratory within a timeframe compatible with their proper clinical use and under conditions of confidentiality allowing professional secrecy to be maintained:
  - The results are sent to the Transmitting Laboratory. Patient' and "prescriber" copies may be identified, but will be sent to the Transmitting Laboratory, which will be responsible for giving them to the patient and the prescriber respectively.
  - Only reports that are required by law to be sent to prescribers are sent directly to them.
- In accordance with the provisions of Article L. 6211-19 of the Public Health Code, the Transmitting Laboratory shall provide the patient and the prescriber with the results report. Where applicable, in the event that a single report is given to the patient and the prescriber by the Transmitting Laboratory, this report shall include the results and interpretations of the CERBA Laboratory (which the CERBA Laboratory expressly authorises) and shall clearly mention the contact details of the CERBA Laboratory. If possible and as necessary, the Transmitting Laboratory can complete the interpretations according to the clinical and biological elements available to it.
- The CERBA Laboratory undertakes to communicate urgent results within a timeframe compatible with patient care.
- For tests defined as 'medical emergencies' in the documentation available on our website and for critical results, biologically validated results are faxed and/or telephoned and/or reported by secure e-mail and/or results server.
- Apart from these cases, for files requested urgently by the Transmitting Laboratory, the biologically validated results are faxed or sent by secure email if this has been requested by the Transmitting Laboratory.
- A daily email alert, which can be set up by the CERBA Laboratory sales department, enables you to receive the list of dossiers including :
  - results which the CERBA Laboratory biologist considers should be processed rapidly and reported to the biologists of the Transmitting Laboratory,
  - files declared urgent by the Transmitting Laboratory,
  - analytical non-conformities,
  - pre-analytical non-conformities,
  - incomplete files.
- The Transmitting Laboratory chooses the method(s) for transmitting the results from among the solutions proposed by the Cerba Laboratory

# A DYNAMIC FOCUSED ON MEDICAL BENEFITS

Advice prior to prescription

Prescribers

Laboratories

« Biomédicalement  
vôtre » podcast on the  
right prescription

Quality samples

Online exam catalogue

Examination  
catalogue integrated  
into customer LIS

Management of  
refusals and  
exemptions

Taking account of the  
clinical context

Clinical information on  
the application forms

Medical prescription  
forms adapted to  
specific collections

Informed consent  
forms

Managing customer  
incompletes on  
Mycerba

Medical emergency  
management

Turnaround times  
compatible with  
requirements

High-performance /  
innovative methods

Production of new  
exams every year

Numerous parameters  
in range B

Parameters with  
several control  
techniques

Reliable and accurate  
results  
(IQC/EQA/ILC,...)

Regular review of  
production capacity

Business continuity /  
recovery plan

Certification as a  
Reference Medical  
Biology Laboratory  
(RMBL)

Consultancy services  
downstream of the  
result

Differentiated  
reporting for patients /  
prescribers /  
laboratories  
(regulatory or ethical)

Conclusions /  
Interpretations /  
Automated or manual  
advice in line with the  
recommendations of  
learned societies

Reminder of the pre-  
criticalana conditions  
on the Minutes

Effective  
communication

Distribution of  
pathological results

HPRIM connection in  
customer LIS

Results server

Customer relations  
department dedicated  
to queries and  
complaints

Real-time updates to  
the examination  
catalogue

lab-cerba.com website

QSE Manual

Contributing to the  
health of all

Cerba Live Session  
scientific webinar

University and  
postgraduate teaching

ANDPC medical  
training

Peer-reviewed  
publications

Participation in MCM  
(multidisciplinary  
consultation meetings)

Collaboration with the  
National Reference  
Centres

Collaboration with  
biotechnology and  
diagnostics companies

Participation in  
public/private clinical  
trials

Participation of  
biologists in expert  
congresses or  
membership of learned  
societies

Respect for medical  
confidentiality and  
privacy

Personal data  
protection policy

Confidentiality charter  
/ Training for new  
arrivals

Anonymisation of  
samples / results for  
studies and  
epidemiology





**CERBA**

[www.lab-cerba.com](http://www.lab-cerba.com)

