

# Quality Manual CRBIP, Biological Resource Center of Institut Pasteur

### Applicable standards:

### ISO 9001:2015

Quality management systems — Requirements

### ISO 20387:2018

Biotechnology — Biobanking — General requirements for biobanking

### ISO 21710:2020

Specifications on data management and publication in microbial resource centers



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### 1. Presentation of the Biological Resource Center of Institut Pasteur

The Biological Resource Center of Institut Pasteur (CRBIP) is a biobank created in 2001 with the mission of harmonizing the management of Institut Pasteur's collections under a common Quality Management System (initially, NF S96-900). It brings together three collection units:

- The "Collection de l'Institut Pasteur" (CIP),
- The Pasteur Cultures of Cyanobacteria (PCC),
- The Collections for Human health of Institut Pasteur (CHIP).

In 2018, a fourth unit joined the CRBIP: the National Collection of Cultures of Microorganisms (CNCM).

Since 2022, a process of integration of the Virus (CVIP) and Fungal (CFIP) collections into the CIP has been in place. A CRBIP Project Management Office (PMO) has been formalized in 2022 with a transversal role in the management of projects - other than internal research projects. Collection managing units are responsible for the biobanking activities related to their specific bio-resources and for their internal research projects.

The CRBIP is located on the campus of the Institut Pasteur in the 15th district of Paris.

The fact of integrating within its scope one of the first collections of microorganisms in the world, the CIP; the Global Reference Collection for Cyanobacteria, PCC; the only IDA (International Depository Authority) collection in France, the CNCM; together with a collection of bio-resources of human origin, CHIP; as well as the fact of being part of Institut Pasteur, give to this center a unique positioning at the national and international level. It also encourages CRBIP to develop a range of professional products and services, and to further develop certain units towards accreditation to the ISO 20387 standard by 2025.

### 1.1. Structure of the CRBIP

The CRBIP brings together four collection units, under a single hierarchical link (Appendix 01 to 06):

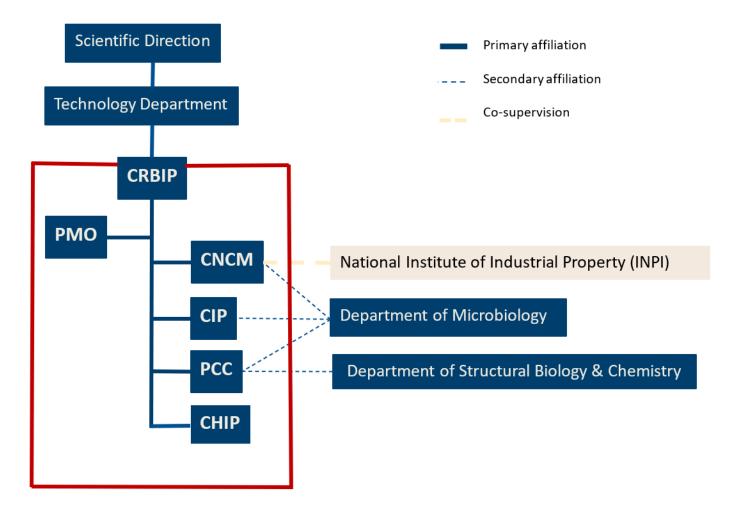
- The CIP (Collection de l'Institut Pasteur) unit was created by Dr. Binot, who began to preserve bacterial strains as early as 1891. For more than a century now, the CIP's premises have been located on the campus of the Institut Pasteur. The CIP hosts a high biodiversity with more than 26,000 bacterial strains belonging to more than 5,000 different species. Freeze-drying has started at CIP in the 1950s.
  - The CVIP (Viral Collection of Institut Pasteur) contains more than 200 viral strains of human origin, including families Flaviviridae, Togaviridae, Picornaviridae, Orthomyxoviridae, Rhabdoviridae and Retroviridae. Most of these viruses are kept in a frozen state, and a few are available freeze-dried. A Subject Matter Expert from the National Reference Center (NRC) "Rabies" (CNR Centre National de Reference Rage) of the Institut Pasteur is assigned to the CVIP.
  - The CFIP (Fungal Collection of Institut Pasteur) aims to reintegrate the strains of yeasts and filamentous fungi (about 2,000 strains) from the former Institut Pasteur's fungal collection "UMIP", which closed in 2013. This historical collection includes specimens of different origins, mainly preserved in mineral oil and in a freeze-dried state. A Subject Matter Expert from the NRC "Invasive mycosis" (CNR Mycoses invasives) of the Institut Pasteur is assigned to the CFIP.
- The PCC (Pasteur Cultures of Cyanobacteria) unit contains a collection of 750 isolated pure strains of cyanobacteria, which represents a large part of the morphological, physiological, and ecological diversity of this phylum.



- The CHIP (Collections for Human health of Insitut Pasteur) unit collects and offers various human biological resources from healthy volunteers and patients to the scientific community, such as: blood and derivatives, saliva, stool, nasopharyngeal swabs, etc., for a total of more than 150,000 samples in stock.

  CHIP supports clinical trials in close collaboration with the Institut Pasteur's Medical Department, in particular the Clinical Research Coordination Center (PC-RC) and the Institut Pasteur Medical Center (CMIP). In addition, this unit hosts collections from research projects that have been completed with the aim to reuse them.
- The CNCM (National Collection of Cultures of Microorganisms) is an international depositary authority (IDA) under the Budapest Treaty for the purposes of national and international patent proceedings. It is the only such unit allowed to collect bacteria, filamentous fungi, yeasts, viruses and animal and human cell lines with this purpose in France. Microorganisms are accepted regardless of whether they are genetically modified or not. The provision of biological material held at the CNCM is governed by the Regulations under the Budapest Treaty.

Finally, a Project Management Office (PMO) is responsible for managing the CRBIP's transversal activities: quality, project development and management, communications, regulatory and normative monitoring, data management, business development.





### 1.2. Activities of the CRBIP

The CRBIP is a solid infrastructure - scientifically and operationally - for microbial and clinical biobanking. It promotes harmonization between CRBIP units, technologically advanced solutions, taxonomic and biospecimen research, leveraging collaboration with internal analytical and data platforms and implementing a strong and harmonized Quality Management System (QMS).

# **Activities of the Biobank** « Biospecimen Science » **Biobanking Operations Knowledge dissemination** Acquisition **Training** Molecular taxonomy, Characterization genomic Participation in and functional analyses Production technical/scientific and Preservation ethical-regulatory Pre-analytical research committees and working Distribution groups Databases Support Activities Human Resources; Infrastructure; Purchase; Information Systems

# <u>Legend</u>:

QMS Scope



### 1.3. List of CRBIP services

### Deposit and Storage

### Microbial strains

- Patent deposit / storage, -80°C and LN2
- Open deposit / storage 12-20°C, -80°C and LN2
- Institutional deposit of bacterial, fungal strains /storage 12-20°C, -80°C, LN2

### • Human biological materials

- Patent deposit of cell lines / storage LN2
- Institutional deposit/storage -80°C and LN2

### Preparation of biological materials

### Bacterial strains

- Culture of fungal strains on solid media
- Culture and maintenance of live pure strains of cyanobacteria
- Freeze drying
- DNA extraction from bacterial pellet

### Human biological materials

- Serum, plasma, urine, saliva, swab medium aliquoting (option in P2+, option automated)
- PBMC isolation and cryopreservation
- DNA extraction from whole blood

### - Characterization of biological materials

### • Bacterial strains

- DNA quantification by spectrofluorometry
- Taxonomic confirmation
  - By MALDI-TOF and/or Illumina WGS
- Single genome analysis (genome <10Mb)</li>
  - QC Bioinformatics Analysis of Genome Sequence
  - Identification and contextualization of sequences of concern
  - Curation of data in the existing cgMLST (core genome Multilocus Sequence Typing)
    database
- Multiple genomic analysis (genome <10 MB)
  - Comparative genome analysis (phylogeny, ANI (Average Nucleotide Identity))
- Support for strain collection
  - Private genomic database and analytical web tools

### Human biological materials

- DNA/RNA quantification and purity analysis by spectrophotometry
- DNA quantification by spectrofluorometry
- PBMC enumeration and viability measurement



### **List of services in development:**

### - <u>Preparation of biological materials</u>

### Bacterial strains

- Culture on solid media in anaerobic conditions
- Culturomics

### • Human biological materials

- Stool aliquoting under anaerobic conditions
- Stool culture in anaerobic conditions
- RNA extraction from whole blood

### - <u>Characterization of biological materials</u>

### Bacterial strains

- Enumeration of viable bacteria (CFU/ml)
- BioLog analyses
- Quantification of bacterial genome copy numbers (dPCR)

### • Human biological materials

- Hemolysis automated evaluation
- Complete Blood Count and CRP measurement
- Urinalysis
- DNA/RNA size analysis by microfluidic electrophoresis



### 2. COMMITMENT OF THE MANAGEMENT

The vision of the CRBIP is to be a reference biological resource center in the field of microbiology and human diseases. The CRBIP values:

- <u>Bioethics</u>: The CRBIP is committed to respect the ethical principles and corresponding national and international regulations applicable within its units. So, the CRBIP units rely on reference texts formalized through the lists of external documents, the modalities and tools put in place at institutional level, such as the ethical charter or the scientific integrity committee.
- <u>Impartiality</u>: To guarantee the impartiality of its activities and more specifically independent access to its biological resources, the CRBIP wished to set up an organization dedicated to this issue. A Sample Access Committee (with a majority of external members) is set up to ensure the impartiality of decisions taken on access requests, particularly for non-renewable resources.
- <u>Confidentiality</u>: Staff are required to respect confidentiality during their activities, especially in situations concerning:
  - The General Data Protection Regulation (teams, researchers, users, donors participating in research, etc.) due to personal data potentially held by certain CRBIP units.
  - Intellectual property related to biological resources or their uses.

The mission of the CRBIP is to preserve and enable access to microbial and human-derived biological samples and associated data and services, to support high-quality and reproducible research by the Institut Pasteur teams and the scientific community at large, and to contribute to the development of research applications.

### 2.1. The Institut Pasteur's Quality, Safety and Sustainable Development policy

The Institut Pasteur must conduct its research, teaching and public health missions with the best Quality of operations while ensuring the health of its staff and respect for the environment. This approach is part of its sustainable development approach, called the Institut Pasteur's Corporate Social Responsibility.

This commitment translates into:

- Control of quality, safety, and sustainable development risks in the conduct of the Institut Pasteur's activities and projects.
- Maintenance and provision of a high level of expertise in quality, safety, and sustainable development for all Institut Pasteur units.
- Compliance with legislation and regulations related to Quality, Safety, and the Environment.
- Provision of all the necessary resources (Appendix 07) for the deployment of projects and a carefully thought through management of Quality, Safety and Sustainable Development resources.



### 2.2. CRBIP's Quality Policy

The CRBIP's Quality Policy echoes and supports the development of the CRBIP's various strategic objectives, which are the improvement of its infrastructure, the increase in the distribution of biological resources and the strengthening of the services provided to the scientists of the Institut Pasteur and their scientific partners.

To achieve these quality improvement objectives, the CRBIP CODIR (Comité de Direction) is committed to:

- Maintain the monitoring and evolution of the Quality Management System within all CRBIP units committed to the ISO 9001 standard, including the quality and conformity of biological materials and associated data.
- Ensure the satisfaction of stakeholders.
- Maintain and improve communication (catalogue, website, satisfaction surveys).

### 2.3. CRBIP Stakeholders

As a biobank in the field of microbiology and human diseases, the CRBIP seeks to meet the requirements of its stakeholders.

Stakeholder Stakeholders		Stakeholder Needs and Expectations		
CRBIP	CRBIP Staff	<ul> <li>Alignment of the units' activity with the strategy and objectives set by the CRBIP</li> <li>Respect for working conditions</li> <li>Assignment of roles, responsibilities, and objectives according to each person's competencies</li> <li>Training and development of skills</li> <li>Transparency, trust, benevolence, impartiality</li> </ul>		
Institut Pasteur	The Institut Pasteur Department: Scientific Department, Medical Department, Technology Department, Research Applications and Industrial Relations Department	<ul> <li>Alignment of the CRBIP's activity with the Institut         Pasteur's strategic plan         Being an essential and growing component of the research projects developed by the research units         Meeting biobanking needs, participating in the development of research protocols         Meeting the needs of research teams by providing them with quality biological resources         Facilitating the grant applications and the development of contracts     </li> </ul>		
	Internal support department	- Precise formulation of the need - Compliance with institutional procedures		
Users/Clients	Academics, private industrial companies) IP or CNR Research Units Co-Investigators and Investigators, Investigator Centers: CMIP, hospitals, CRO, learned societies Networks and consortia	<ul> <li>Flexibility, scientific and operational processes associated with Customer orientation and integrated with the Quality Management System (QMS).</li> <li>Availability of reliable, standardized biobanking infrastructure and operations for the reception, storage, and redistribution of biological resources under optimal and controlled conditions.</li> <li>"Fit for purpose" biological resources</li> <li>Support in the management of complex research projects.</li> </ul>		



Stakeholder Category	Stakeholders	Stakeholder Needs and Expectations	
Competent Authorities	Ministry of Higher Education, Research and Innovation SGDSN (General Service for Defence and National Security) CPP, CNIL Ministry of Solidarity and Health, ANSM, HAS	- Compliance with regulatory requirements	
Sample Access External Members, Internal Members		- Annual reporting on CHIP's activities	
Civil society	Research Participants	<ul> <li>Compliance with good clinical practices (deontology, ethics, confidentiality) and informed consent</li> <li>Involvement in the design and evolution of projects impacting them</li> <li>Right to change or revoke informed consent</li> </ul>	
Networks and other external partners	3-CR, BBMRI, MIRRI, WFCC, ECCO, GBIF, Nagoya Expert Group, ISBER, WHO (Appendix 08)	<ul> <li>Participation in the evolution of the activity within the network</li> <li>Sharing knowledge and experience</li> <li>Reflection on specific themes via working groups</li> </ul>	
Suppliers / External service providers of the Institut Pasteur	Suppliers of hardware, consumables, solutions and services related to the biobanking business P2M platform	<ul> <li>Precise formulation of the need</li> <li>Compliance with established procedures and commitments</li> <li>Customer loyalty / Relationship of trust</li> </ul>	



### 3. QUALITY MANAGEMENT SYSTEM

The use of standardized procedures for the collection, preparation, storage, and distribution of biological materials is necessary to ensure that samples can be used in a compliant, "fit" and reproducible manner. The use of standardized procedures is a key requirement to ensure the quality of results, eliminating pre-analytical variations and bias. Therefore, the CRBIP is committed to managing its operations under the control of a Quality Management System (QMS).

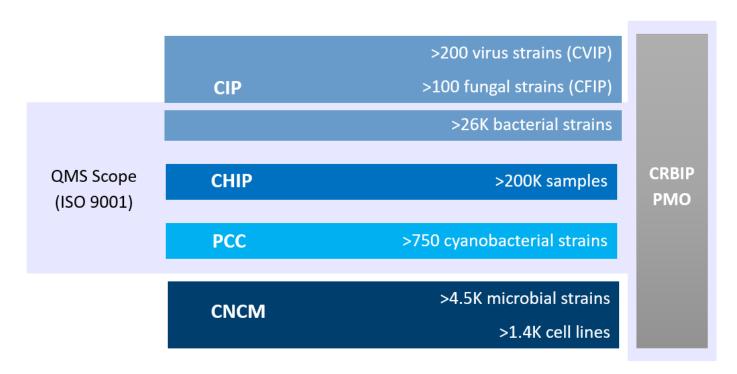
The CRBIP Management delegates to the CRBIP Quality Manager the organization and the continuous improvement of the CRBIP Quality Management System, in collaboration with the Quality Engineer of the Institut Pasteur Quality Department (affiliated to the Technical Resources and Environment Department of the Institut Pasteur). The Quality Manager also coordinates actions with the various Quality Liaisons of the units that constitute the CRBIP.

### 3.1. Scope of the QMS

The QMS of the CRBIP covers the activities of acquisition, production or preparation, quality control or characterization, preservation/storage and distribution of biological resources, microorganisms, and human biological samples. It applies to all three units: CRBIP-PMO, CIP, PCC, and CHIP.

Following the end of the certification cycle according to NF S 96-900, the CRBIP follows the ISO 9001:2015 standard while preparing for ISO 20387:2018 accreditation.

Chapter 8.3 "Design and development of products and services" of ISO 9001 is excluded from the scope.



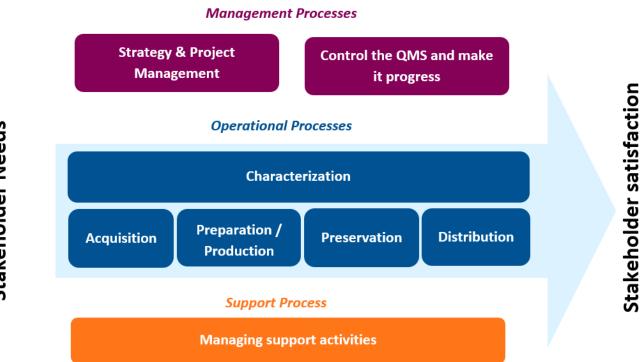


### 3.2. CRBIP Process Mapping

The management processes (Appendix 09) are focused on listening to and respecting the needs and requirements of stakeholders in accordance with applicable laws and regulations. The quality policy and quality objectives are in line with the CRBIP's strategy and form the basis for the quality and continuous improvement of the CRBIP.

This strategy is also risk-based and continuous monitoring of performance, effectiveness, compliance, and client satisfaction ensures evidence-based decision-making and continuous improvement of the organization.

The operational processes are composed of the following stages: acquisition, preparation/production, preservation, distribution, and a transversal process of characterization/quality control of the biological resources deployed across all operational stages.





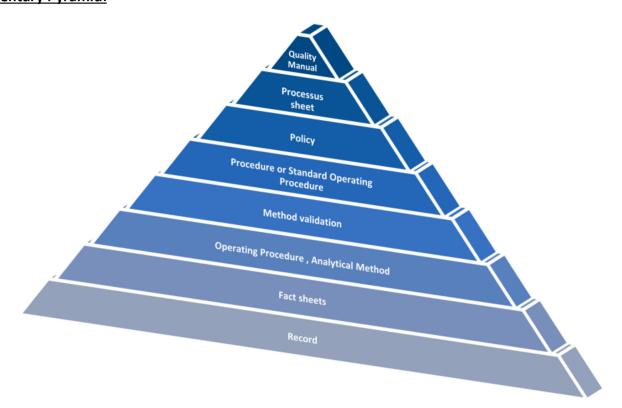
### 3.3. Document management

The CRBIP uses a document management system that corresponds to the various processes of the CRBIP and is built to comply with the normative requirements: ISO 9001:2015 and ISO 20387:2018.

Process	Abbreviation	Wording
Strategy & Project Management	PM	Project Management
Control the QMS and make it progress	MANQ	Quality Management
Characterization	CHAR	Characterization
Acquisition	ACQ	Acquisition
Preparation / Production	PRE	Preparation
Preservation	CON	Conservation
Distribution	DIS	Distribution
	HSE	Health & Safety
	EQP	Equipment
Managing support activities	ACH	Purchase
	INF	Computer science
	RH	Human Resources (Skills Maintenance)

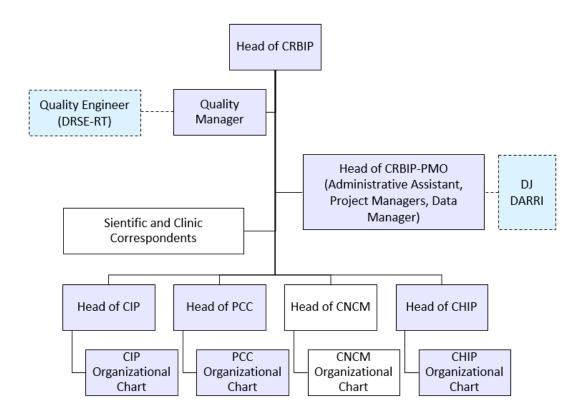
Document management related to the Institut Pasteur's cross-functional institutional processes is described in the institutional procedure "Document management and control of recordings". Regarding the document management of the CRBIP, additional specifications are applied and described in the CRBIP document CRBIP\_MANQ\_PO\_001\_Gestion procedure. The general documentation of the CRBIP is available on the SMQ software "Kalilab", document management tool.

### **Documentary Pyramid:**





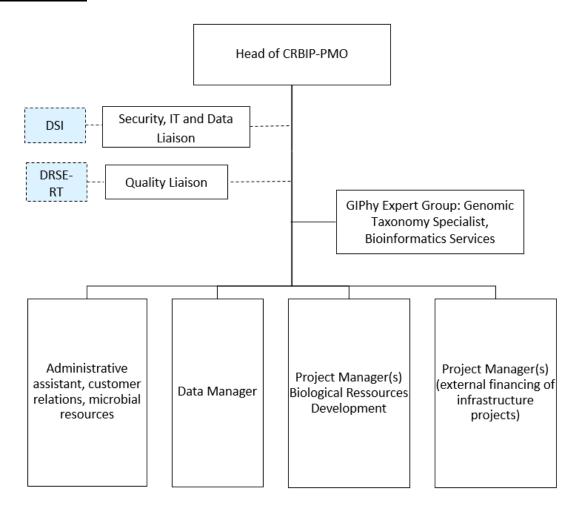
# **APPENDIX 01: CRBIP ORGANIZATIONAL CHART**



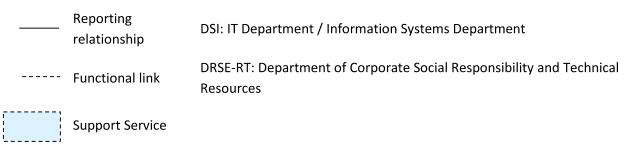
<u>Legend</u> :		DARRI	Technology Transfer and Industrial Partnership Department
	Reporting relationship	DJ	Legal Department
	Functional link	DRSE-RT: Department of Corporate Social Responsibility and Technic Resources	
	Support Service		QMS Scope



# **APPENDIX 02: CRBIP-PMO ORGANIZATIONAL CHART**

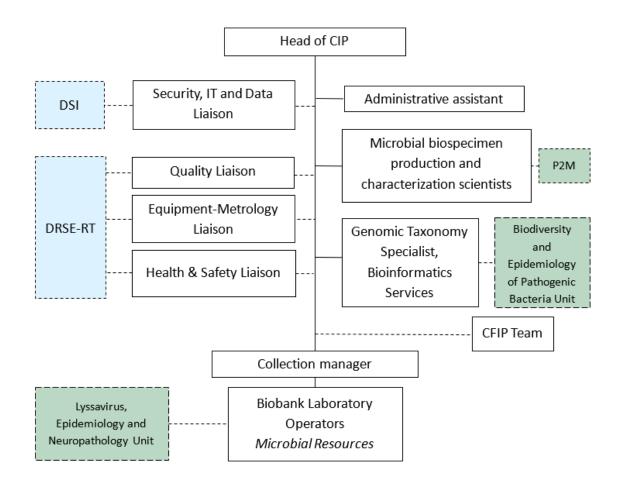


### Legend:





# **APPENDIX 03: CIP ORGANIZATIONAL CHART**

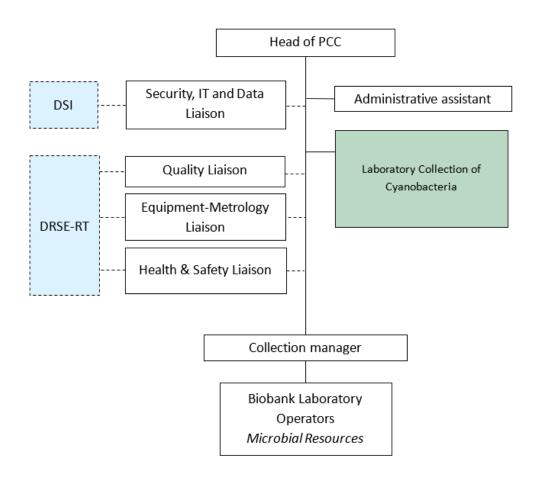


# Legend: Reporting relationship DRSE-RT: Department of Corporate Social Responsibility and Technical Resources DSI: IT Department / Information Systems Department Support Service Subject Matter Expert

P2M Shared Microbiology Platform



# **APPENDIX 04: PCC ORGANIZATIONAL CHART**



### Legend:

Reporting relationship

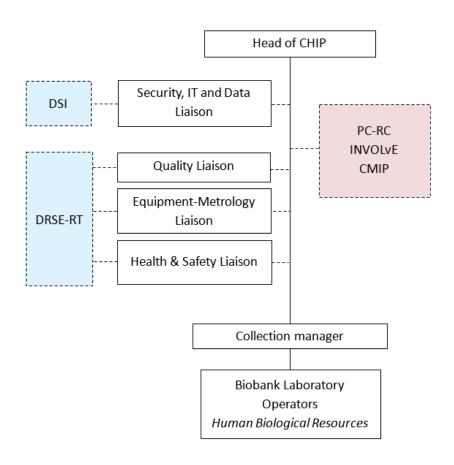
DRSE-RT: Department of Corporate Social Responsibility and Technical Resources

DSI: IT Department / Information Systems Department

Support Service



# **APPENDIX 05: CHIP ORGANIZATIONAL CHART**



### Legend:

Reporting relationship

----- Functional link

DRSE-RT: Department of Corporate Social Responsibility and Technical Resources

DSI: IT Department / Information Systems Department

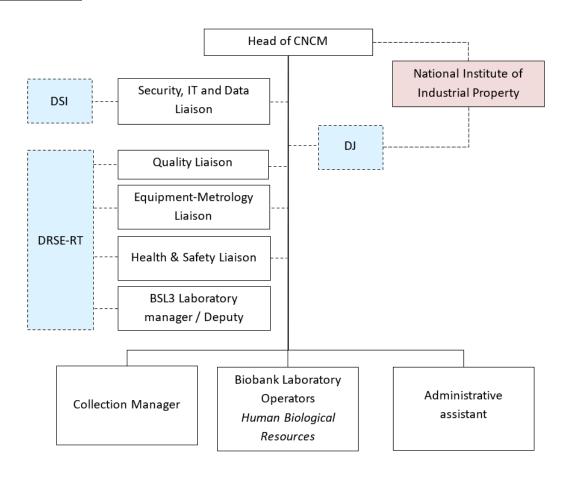
PC-RC: Clinical Research Coordination Center

INVOLVE: Clinical Investigation Center

CMIP: Medical Center of the Institut Pasteur



# **APPENDIX 06: CNCM ORGANIZATIONAL CHART**



## Legend:

----- Reporting relationship
----- Functional link

DRSE-RT: Department of Corporate Social Responsibility and Technical Resources
DSI: IT Department / Information Systems Department

DJ: Legal Department

Co-tutorship



# **APPENDIX 07: INSTITUT PASTEUR'S INTERNAL PARTNERS**

Management of the Institut Pasteur	Mission	
General Direction	Institut Pasteur's Quality Policy and Strategic Orientation	
Medical Department	Development of medical research, strengthening of public health	
	activities, organization of partnerships with hospitals and medical	
	research structures, advice and evaluation of international medical and	
	scientific affairs	
Human Resources Department	Administration of personnel files, recruitment and mobility,	
	implementation of training plans	
Legal Department	Design and validation of MTA (Material Transfer Agreement), validation of General Sales Conditions, legal formatting and finalization of contracts negotiated by DARRI, legal monitoring and application of legislative and regulatory texts on microbial collections (e.g., Nagoya, Budapest Treaty) and human collections (e.g., Jardé Law), other legal	
F	missions	
Finance Department	Budget management, cost analysis, purchase orders, new customer creation, sales invoicing	
Training Center	Management of teaching activities on biodiversity of microorganisms	
Task as last Transfer and Industrial	and biobanking	
Technology Transfer and Industrial Partnership Department (DARRI)	Negotiation of the contractual conditions with the industry partners, of the IP patent deposits	
Scientific Evaluation Department (DES)	Evaluation of Scientific Units	
International Department -	Collaboration in the scope of the RIIP organizations holding collections	
International Network of Institut		
Pasteur (RIIP)		
Information Systems Department	Design and management of software and other database management	
	tools	
	Data backups	
Colombific Company Domentus and (DCC)	Management of interfaces between information systems  Evaluation of Scientist careers	
Scientific Careers Department (DCS)		
General and Scientific Secretariat	Management of the "Research" website	
(SGS) Communication and Sponsorship	Implementation of decisions after evaluation of research units  Management of the "Public Health" website	
Department	Management of the Public Health Website	
•	Drangustion of sulture modic Comics, Drangustion of sulture modic	
Department of Corporate Social Responsibility and Technical	<u>Preparation of culture media Service</u> : Preparation of culture media, preparation and distribution of laboratory glassware and consumables	
Resources (DRSE-RT)	, , , , , , , , , , , , , , , , , , ,	
Resources (DRSL-RT)	<u>Technical Services</u> : Maintenance, intervention and upkeep of equipment, "OCEASOFT" management, printing of informative material	
	(brochures, posters, etc.) for communication	
	Risk Prevention Department: Training in the prevention of biological,	
	chemical and other risks, assistance in the application of regulatory	
	requirements and controls (GMOs (Genetically Modified Organisms),	
	MOTs (Toxins and Microorganisms), etc.)	
	Quality, Environment and Sustainable Development Department:	
	Support, advice and facilitation for the QMS, organization of audits,	



Management of the Institut Pasteur	Mission	
	Kalilab tool administrator, management of general procedures,	
	metrological services, cleaning services, training/awareness-raising	
	Logistics and Security Department: reception of shipments, collection	
	and dispatch of products, mail management, shipments-out	
Archives service	Archiving of paper records, study documents, medical records	
Technology Department	Main affiliation of CRBIP, strategic collaboration in projects for the	
	development of new technologies, support for projects requiring	
	bioinformatics expertise (Hub C3BI - Bioinformatics and Biostatistics)	
Grant Office Department	Monitoring and support for responding to calls for proposals (national,	
	European and international)	



# **APPENDIX 08: CRBIP PARTICIPATION IN NETWORKS AND INFRASTRUCTURE**

**France** 

**Club 3C-R** (The Biological Resources Network)



**IBISA** (Infrastructures in Biology, Health and Agronomy)



**GIS CYANOBACTERIES** 



**Europe ECCO** (European Culture Collections' Organisation)



**MIRRI-ERIC** (Microbial Resource Research Infrastructure)



### International

**ISBER** (International Society for Biological and Environmental Biorepositories)



**WFCC** (World Federation for Culture Collections)





# **APPENDIX 09: DESCRIPTION OF THE CRBIP PROCESSES**

Process	Input data	Actions / Purpose of the process	Output data
Strategy &	Institut Pasteur Strategic Plan	- Define the strategic directions of	Quality Manual
Project	CRBIP Strategic Plan	the CRBIP and enforce them.	Management Review
Management	Institut Pasteur Quality Policy	- Define and monitor the strategic	Quality Reviews
	CRBIP Quality Policy	projects of the CRBIP.	Communication documents
	Financial Plan		Project Briefs
	European projects		List of projects
	Listening to PIs (Principal		3-5-year strategic plans of
	Investigators) (needs and		Units
	expectations)		
	Biological Resources		
	Application Form		
	Regulatory, scientific and		
	technical monitoring		
	Management Review n-1		
	Quality Reviews n-1		
QMS	Incidents	- Coordinate the entire CRBIP to	Table for follow-up of
monitoring and	Complaints	advance the QMS.	improvement actions
progress	Internal Audits / External	- Measure indicators and	Annual Internal Audit
	Audits	incidents and draw up corrective	Program
	Risk Analysis	and preventive actions.	Indicator Tracking Table
	Listening to Interested Parties		
	(feedback, emails, proposals,		
	opportunities)		
	Satisfaction surveys		
	Objectives and Indicators		
	Supplier/Provider Evaluations		
Acquisition	Cyanobacteria deposit (PCC)	- Enrich collections with new	Passaging
	Deposit Forms (CIP/CNCM)	strains/samples of human origin.	Culture
	Biological Resources Request	- Establish a computer database	Production
	Forms / Sample processing	and/or catalogue covering each of	Distribution
	Forms / Documents	the collections.	Updated BIMS
	Associated with Closed		
	Collections (CHIP)		
Preparation /	Documents related to the	- Prepare/Produce samples or	Biological material and
Production	protocol of the collection	derivatives from primary	associated data (Secondary
	concerned or of the	biological resources and their	samples stored, Strains
	application	associated data according to the	produced, Strains passaged)
	Acquired bioresources	work instructions pre-established	Updated BIMS
	Passaging schedule and	in the protocol documents of the	
	Passage Sheet (PCC)	relevant collection.	
	Production Planning and	- Obtain enough biological	
	Production Sheet (CIP)	material.	
	BIMS		
Preservation	Biological material and	- Guarantee the quality of	Biological material and
	associated data	biological material (controls).	associated data



Process	Input data	Actions / Purpose of the process	Output data
	Preparation Sheets (CHIP) Production Sheets / Control Sheet (CIP) Passage Sheet (PCC) BIMS	- Control traceability from acquisition to distribution.	Specification Sheet (PCC) Production Sheet / Control Sheet (CIP) Census of Biological Collections File (CHIP) Updated BIMS
Distribution	Catalogue Purchase orders Request for Access to Biological Materials Biological material Related data	Ensure the distribution of biological materials in accordance with applicable procedures.	Creation of a new customer account if not existing Creation of an order and invoicing number via the accounting management tool Assigning a budget line Parcels and related data Shipping Requests via the Shipment Management Tool Customs documents, delivery notes (CIP / CHIP) Contacts of users
Characterization	Biological material and associated data Reference material Non-Compliance / Complaint Periodic QC Plan	Guarantee the quality of biological material through controls.	QC Worksheet or Report Production Sheet / Control Sheet (CIP) Technical Form (CHIP) Passage Sheet (PCC) LIMS
Managing support activities	Institut Pasteur Strategic Plan CRBIP Strategic Plan Management Review Quality Reviews Needs of the CRBIP	Ensure the availability of the necessary resources for the implementation of the activities of the CRBIP: - Manage Human Resources - Manage equipment, consumables, import/export, cleaning, waste, media and material - Manage Financial Resources - Manage Information Systems - Manage the regulatory and legislative framework - Provide support for scientific projects using human biological samples and procedures requiring ethical-regulatory compliance.	Human resource: Job description / Job description Flowcharts Task Breakdown Charts Professional Annual Maintenance Carried Out Trainings carried out and evaluated DRSE-RT: Completed equipment files (equipment folder, maintenance, mapping, etc.) Completed Materiel Management Tables Batch Tracking Supplier / Provider Reviews Collaborative Agreements Finance: Annual Budgets Allocated to Projects / Invoices Information systems:



Process	Input data	Actions / Purpose of the process	Output data
			Collection Management
			Software
			Catalogues
			Computer equipment
			Data protection
			Collaboration Agreement
			<u>Legal</u> :
			GDPR
			MTA (Material Transfer
			Agreement)
			IP-INPI Contract, Form and
			Contract for the Deposit of
			Biological Materials (CNCM)
			PC-RC:
			Research protocols (CHIP)