QUALITY MANUAL

Research Institute I3Bs and its subunits

Revision number: 0	Reason for Revision:	Date: 16/11/2011	Approved by : Director
Revision number: 1	Reason for Revision: -Removal of names from the organigram -Changed some SOPs to TOPs	Date: 12/01/2012	Approved by : Director
Revision number: 2	Reason for Revision: - Updated scope of the QMS and quality policy	Date: 14/02/2013	Approved by : Director
Revision number: 3	Reason for Revision: - Updated processes sequence and interactions -include responsibilities of the process responsible -include table of inputs and outputs of the processes	Date: 03/04/2013	Approved by : Director
Revision number: 4	Reason for Revision: - Updated organigram (include IP manager) - include table of inputs and outputs of the processes	Date: 12/11/2014	Approved by : Director
Revision number: 5	Reason for Revision: - Updated Quality policy and the Sequence of the processes (include knowledge management and strategic management)	Date: 19/01/2017	Approved by : Director
Revision number: 6	Reason for Revision: - Creation of I3Bs Organic Unit and corresponding internal reorganization	Date: 07/06/2019	Approved by : President and Directors
Revision number: 7	Reason for Revision: - Update Quality Policy	Date: 04/02/2020	Approved by : President and Directors
Revision number: 8	Reason for Revision: - The number of processes was reduced to 8	Date: 07/05/2021	Approved by : President and Directors

QMS Manual Index

Promulgation of the Quality Management System Manual

The present manual describes the means and procedures adopted by the I3Bs – Research Institute on Biomaterials, Biodegradables and Biomimetic, Organic Unit of University of Minho, and its Subunits, to assure the quality of Research and Services performed and the management of its Quality System.
This manual also describes the organization and the functioning of the Management Systems in order to assure the fulfillment of the Quality Policy.

As the Quality concerns all collaborators, it is each one duty, according to his/her specific involvement in the Management System, to contribute to the fulfillment of the requirements stated in this Manual.

The Presidency of the Research Institute I3Bs and the Directors of both Subunits defined the Quality Policy and will be committed to its fulfillment and continuous improvement.

Barco, Guimarães, 7th of May 2021

The President of the Research Institute I3Bs

The Director of the 3B's Services and Innovation

The Director of the 3B's Research Group

1. Introduction

1.1. Objective of the Quality System Manual

The Quality Management System Manual presents a summary of the methodologies adopted by the Research Institute I3Bs and its subunits, to assure the application of the NP EN ISO 9001:2015 Guideline to the management of its processes and resources concerning the Quality, promoting the satisfaction of the costumers and other parts interested in the Institute activities.

1.2. Organization of the Quality System Manual

The Quality Manual, composed of 10 pages, is elaborated by the Quality Management System (QMS) Responsible, reviewed and approved by the President of the Institute and the Directors of the subunits. Only the initial page (promulgation) is signed. In the pages' footnote, it's indicated the revision number and date, the indication of "Reproduction forbidden", indication of who approves and the page number.

1.3. Scope of the Quality Management System

The QMS concerns to all the services on research projects on new materials and stem cells technologies for the biomedical sector, as well as technical services and consulting for companies and research institutions provided by the Research Institute I3Bs and its subunits.

1.4. Responsibilities for the implementation and maintenance of the Quality System Manual

All the collaborators of the Research Institute I3Bs, and its subunits, are responsible for the application and continuous improvement of the Quality Management System.

1.5. Management Representative

The Research Institute I3Bs Presidency and the Directors of its subunits nominated Vitor M. Correlo, as their representative for the Management of the Quality Management System, with the objective of making the system effective and efficient. He has the responsibility and full authority to audit the conduction of processes and follow them up.

1.6. Quality Policy

The I3Bs – Research Institute on Biomaterials, Biodegradables and Biomimetic, and its subunits, are composed of an international multidisciplinary team devoted to development new therapies and solutions to be used on a range of biomedical and environmental applications. The Presidency of the Institute and the Directors of both Subunits assume the commitment of continually improve the quality of the research carried out, in the perspective of generating knowledge that can be used in successful outcomes to improve the quality of life of patients worldwide.

The Presidency of the Institute and the Directors of both Subunits, considers the customer as the focus of its performance and for this reason, the identification of the customer's needs and expectations is a commitment that must be assumed in a perspective of continuous improvement, based on the following directives:

- Guarantee the fulfilment of ISO9001:2015 objectives and requirements; Generate and manage un-existent knowledge in the research fields addressed by the Institute
- Cleary identify the customer's needs and fully satisfy their expectations
- Assure the conformity of the services performed according to the pre-established specifications, in accordance to the agreed deadlines
- Establish partnerships with the suppliers to assure the adequate supply of products and services
- Promote the satisfaction of the collaborators and researchers, from a personal and professional perspective
- Provide and adapt the necessary resources for the continuous improvement of the work environment, preventing accidents and assuring good conditions for the health and safety of the people that works in our Organization, according to the applicable legislation.

The Presidency of the Institute and the Directors of both Subunits assumes the responsibility for the implementation of this Policy.

2. Presentation of the Organization

2.1. Localization

3B´s Research Group - Biomaterials, Biodegradables and Biomimetics
University of Minho
Headquarters of the European Institute of Excellence on Tissue Engineering and Regenerative Medicine
AvePark, Zona Industrial da Gandra
4805-017 Barco
Guimarães, Portugal

2.2. Brief history

- In 1998, the 3B's Research Group – Biomaterials, Biodegradables and Biomimetics of University of Minho was established by Prof Rui L. Reis.

  The group is an international multidisciplinary team devoted to development and processing of new materials to be used on a range of biomedical and environmental applications. Its research focuses the use of novel polymeric and composite biomaterials from natural origin such as carbohydrates and mainly from renewable resources (starch, casein, soy, chitin, chitosan, algae, and silk fibroin among others) for scaffolds production by non-conventional processing methodologies.

  Several biodegradable systems have been proposed by this group and others are being studied for applications related with bone replacement and fixation, tissue engineering scaffolding and tissue regeneration, systems for controlled delivery of drug or bioactive agents.

- In 2008, the group moved to the headquarters of the Institute of Excellence for Tissue Engineering and Regenerative Medicine Research which results from the EXPERTISSUES NoE and has branches in 20 different locations around Europe. This new facility is located in the S&T Park – AvePark (Barco, Guimarães, Portugal) and it is fully equipped for performing cutting-edge research on tissue engineering.
- In 2018, 3B's Research Group become an organic unit of the University of Minho entitled I3Bs - Research Institute on Biomaterials, Biodegradable and Biomimetics (with bylaws similar to the other Schools of University of Minho). This advancement imposed an internal rearrangement of the I3Bs in two sub-units:

  - 3B's Research Group
  - 3B's Innovation and Services

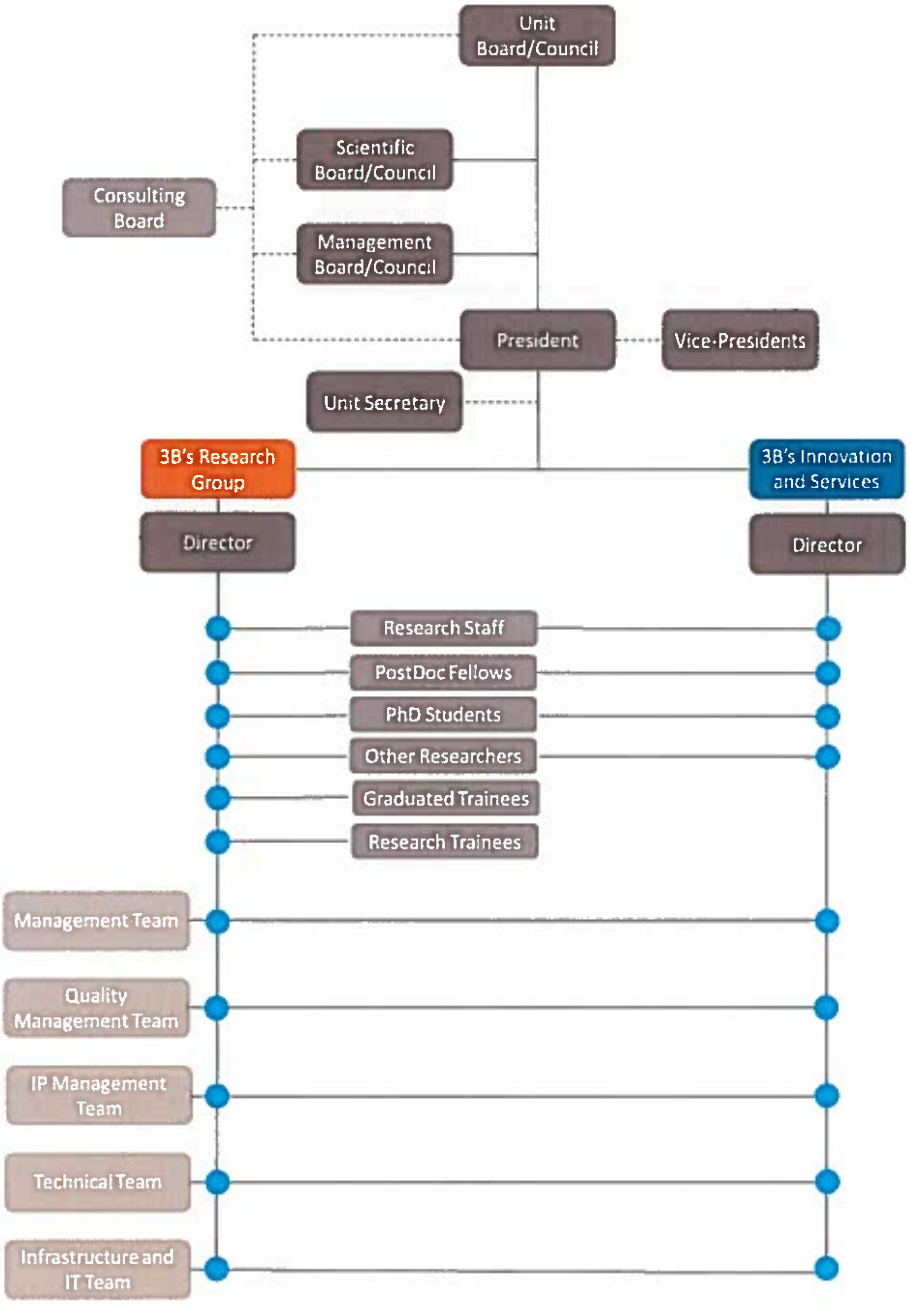
2.3. Collaborators and infrastructures

The Research Institute I3Bs, and both Subunits, have human resources adequate to their activities, including researchers with various backgrounds, lab technicians/informatics staff and a management team, that all together assure the competence for conducting the processes of the Institute I3Bs, and both Subunits.

The Institute I3Bs, and both Subunits use an external company for the billing services provided by A4TEC.

The infrastructures of the Institute, divided into laboratories and office rooms, are adequate to all the activities included in the scope of the Certification.

2.4. Organigram



2.5. Function description

The detailed description of the functions and competences of members of the Institute and both Subunits is included in the SOP005.

Concerning the authority, it is defined that the President and both Directors are the only ones that can make critical decisions related to the Quality. Concerning the daily control of the activities in each area, are managed by the respective responsible that have the authority to adopt the adequate measures, after previously information/agreement with the President and both Directors.

The main communication vehicle of the Institute and both Subunits is the e-mail. Anytime new/updated documentation item is uploaded in the 3B's platform, an alert message is generated and directed to all or to specific persons, according to the uploaded item. Its important refer that the Quality management team has meetings each trimester to follow up the QMS performance.

3. Organization of the Quality Management System

3.1. Types of processes and responsibilities

Three types of processes are considered, with the following definitions.

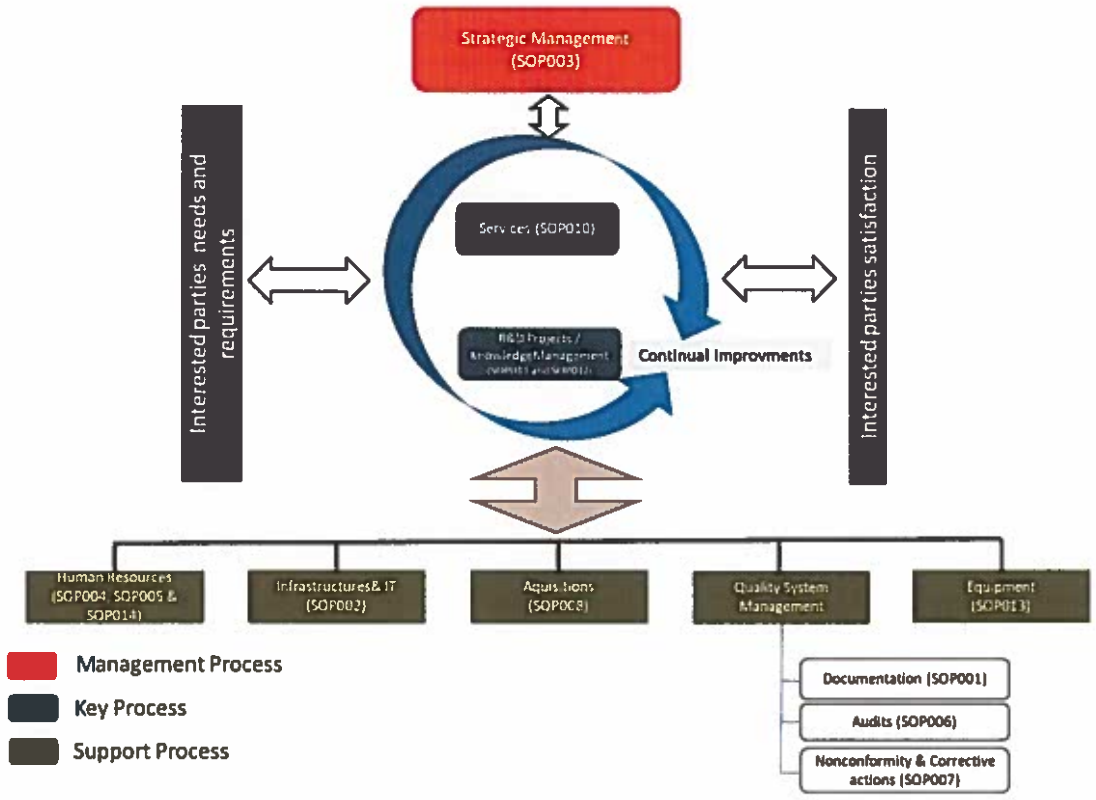
- Key process: process that is included in a sequence that starts and ends in the costumer.
- Support process: process that is fundamental to the performance of the key processes.
- Management process: administrative, accounting or general monitoring process (not classified as key process)

The processes are supported by the Standard Operating Procedures (SOPs), Technical Operating Procedures (TOPs), Equipment's Operating Procedures (EOPs), Biology Research Methods (BRMs), and Materials Research Methods (MRMs), as defined in the SOP for Management of QMS Documentation (SOP001)

Each process has a responsible (named bellow) which has the following responsibilities:

- Assure/manage the adequate documentation for the process
- Define tasks and objectives
- Evaluate results
- Stimulate the continual improvement

3.2. Sequence and interaction of the processes



3.3. Inputs and outputs of the processes

Input source	Input	PROCESS			Output	Output destination
		Designation	Responsible	Associated procedures		
All other processes	• Audit results • Customer information • Process performance and product conformity • Status of the corrective and preventive actions and follow up of actions resulting from previous management reviews • Changes that might affect the QMS • Recommendations for improvements • QMS indicators and objectives follow up	Strategic management	President and Directors of both subunits	SOP003	• Improvement of efficacy of the quality management system and processes • Goals and milestones • Training needs • Indicators • Audit plan • Improvement of the product with client requirements • Resources needs	All other processes
Client	• New external service • External service request	Services	Director of the subunit 3B's Innovation and Services	SOP010	• New EOP and/or MRM and/or BRM for a new test • Invoice emission • Result from the service • Evaluation by the client • Services executed and reported to client (report)	• Answer to the client • SOP010 • QMS • Financial department • Client
Financial entities (EC, CCDRN, FCT, other...) Organisation management	• Opportunities (open call invitations, etc...) • Decisions about project applications • Request from financing entities	R&D Projects / Knowledge Management	President and Directors of both subunits	SOP011 & SOP012	• Submitted project proposal • Study plans (QR34) • Information provided to financing entities • QR36	Financial entities (EC, CCDRN, FCT, other ...) • Organisation management
Market (researchers, ...) Occupational Health, Safety and Environment	• Background/initial competences of admitted collaborators • Initial needs required for the functions assumed • New needs of the organization (from all the processes) • Call for new collaborators (researchers) • Infrastructures (Collective Protective Measures) • Personal Protective Equipment Medical Aptitude Sheets	Human resources	President and Directors of both subunits	SOP004, SOP005 & SOP014	• Annual training plan (QR12) • Training certificate (QR10) • Monitoring of safety and Health • Air Monitoring • Equipment Monitoring	All processes
Need of new equipment	• New equipment acquired • Equipment to repair in external • Performance of the equipment	Equipment	President and Directors of both subunits and Lab Manager	SOP013	• Maintenance and monitoring of equipment • Installation of new equipment	• Equipment for research and services SOP011 SOP001 SOP005
New facilities and changes in the Infrastructures	• New facilities • Update and/or adapt existing facilities • IT management	Infrastructures & IT	President and Directors of both subunits and IT Responsible	SOP002	• Maintenance and monitoring of the infrastructures • Remodelling and update of existing facilities • 3B's platform updating • Website monitoring and update	• Infrastructures for research and services SOP011 SOP001 SOP005
New suppliers New products	• Purchase needs New supply Stock reposition • Product supplied and technical information	Acquisitions	President and Directors of both subunits and Lab Manager	SOP008	• Consult/search to the supplier's market • Orders confirmed to suppliers • Products approved and available in the storage	• SOP011 • SOP002 • SOP005
Evolution of the activities of the organisation Evolution of the standards requirements	• Internal audit plan • External and internal audits report • Audit plan • Information on complains • Information on non-conformities • Information on corrective and preventive actions to be implemented • Information on the results from the evaluation of client satisfaction	Quality Management System	President and Directors of both subunits and QMS Responsible	SOP001 SOP006 SOP007	• Operational audit report • Corrective action plan • Preventive actions plan • SOPs, EOPs, TOPs, MRNs, BRMs	All Processes

3.4. Structure of the Quality Management System Documentation

The documentation necessary for the implementation and maintenance of the QMS can be divided in three levels, according to the following scheme. The first level includes all the mandatory documentation for the fulfillment of the Guideline of reference requirements. In the second level are considered the documents that are complementary to the documentation included in the first level, describing with more detail the activities/tasks of the institution, describing technical specifications and describing the tasks of the collaborators. The third level corresponds to the acquired data and to the evidences of the activities, products or services of the Institute and both Subunits.

Level	Document	Objective
I	Quality Policy	Indicate the commitments assumed and describe strategic guidelines
	Quality Management System Manual	Indicate the scope and the application of the 3Bs guidelines of reference; describe and systematize the developed activities and their historic.
	SOPs	Fulfill the Guideline requirements that must be documented or other necessary QMS documentation.
	Guidelines and regulations	Identify and fulfill the Legislation applicable and other requirements/guidelines adopted.
II	TOPs	Standard procedures related to training in specific labs or equipment's, and proper use of logbooks, proper use of the 3Bs web platform and organization and storage of publications for
	MRMs	Standardize procedures related to materials development and characterization for enhanced reproducibility and accuracy of results
	EOP's	Procedures for proper operating equipment's and thus obtaining more accurate data/ minimize risks of inappropriate use.
	BRMs	Standardize procedures related to biological studies, for enhanced reproducibility and accuracy of results
III	Templates	Standardized form for collection of data.
	Documented information	Evidence the activities developed in the QMS

3.5. Quality Management System Index

QMS index

Requirements		Document/Record associated
4. Context of the organization		
4.1	Understanding the organization and its context	QM, QP, SOP003
4.2	Understanding the needs and expectations of interested parties	QM, QR84, SOP003
4.3	Determining the scope of the quality management system	QM, QP, SOP003
4.4	Quality management system and its processes	QM. SOP003
5. Leadership		
5.1	Leadership and commitment	QM, QR86, SOP003, SOP005
5.2	Policy	All processes
5.3	Organization roles, responsibilities and authorities	QM, QP, SOP003, SOP005
6. Planning		
6.1	Action to address risks and opportunities	All processes
6.2	Quality objectives and planning to achieve them	All processes
6.3	Planning of Changes	All processes
7. Support		
7.1	Resources	All processes
7.2	Competence	SOP002, SOP005, SOP010, all processes
7.3	Awareness	All processes
7.4	Communication	SOP010, QP, SOP003
7.5	Documented information	QR05, SOP001
8. Operation		
8.1	Operational planning and control	SOP003
8.2	Requirements for products and services	SOP008, SOP010
8.3	Design and development of processes and services	SOP010, SOP011
8.4	Control of externally provided processes, products and services	QR24, SOP008, SOP010
8.5	Production and service provision	SOP010, SOP011
8.6	Release of products and services	SOP010, SOP011
8.7	Control of nonconforming outputs	QR26, SOP007
9. Performance Evaluation		
9.1	Monitoring, measurement, analysis and evaluation	QR24, QR25
9.2	Internal Audit	QR11, QR44
9.3	Management review	QR53, SOP003
10. Improvement		
10.1	General	All processes
10.2	Nonconformity and corrective action	SOP007, QR26
10.3	Continual Improvement	All processes

QM: Quality Manual
QP: Quality Policy
SOP: Standard Operating Procedure
TOP: Technical Operating Procedures
EOP: Equipment Operating Procedures
MRM: Materials Research Methods
BRM: Biology Research Methods