# QUALITY MANUAL

## Research Institute 13Bs and its subunits

<table>
<thead>
<tr>
<th>Revision number</th>
<th>Reason for Revision</th>
<th>Date</th>
<th>Approved by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Reason for Revision:</td>
<td></td>
<td>Director</td>
</tr>
<tr>
<td>1</td>
<td>Reason for Revision: - Removal of names from the organigram - Charged some SOPs to TOPs</td>
<td>16/11/2011</td>
<td>Director</td>
</tr>
<tr>
<td>2</td>
<td>Reason for Revision: - Updated scope of the QMS and quality policy</td>
<td>12/01/2012</td>
<td>Director</td>
</tr>
<tr>
<td>3</td>
<td>Reason for Revision: - Updated processes sequence and interactions - include responsibilities of the process responsible - include table of inputs and outputs of the processes</td>
<td>02/02/2013</td>
<td>Director</td>
</tr>
<tr>
<td>4</td>
<td>Reason for Revision: - Updated organigram (include IP manager) - include table of inputs and outputs of the processes</td>
<td>03/04/2013</td>
<td>Director</td>
</tr>
<tr>
<td>5</td>
<td>Reason for Revision: - Updated Quality policy and the Sequence of the processes (include knowledge management and strategic management)</td>
<td>03/05/2013</td>
<td>Director</td>
</tr>
<tr>
<td>6</td>
<td>Reason for Revision: - Creation of 13Bs Organic Unit and corresponding internal reorganization</td>
<td>06/06/2019</td>
<td>President and Directors</td>
</tr>
<tr>
<td>7</td>
<td>Reason for Revision: - Update Quality Policy</td>
<td>01/02/2020</td>
<td>President and Directors</td>
</tr>
<tr>
<td>8</td>
<td>Reason for Revision: - The number of processes was reduced to 8</td>
<td>01/02/2021</td>
<td>President and Directors</td>
</tr>
<tr>
<td>9</td>
<td>Reason for Revision: - Include the communication plan</td>
<td>06/07/2022</td>
<td>President and Directors</td>
</tr>
</tbody>
</table>
QMS Manual Index

Introduction

1.1. Objective of the Quality Management System Manual
1.2. Organization of the Quality System Manual
1.3. Scope of the Quality Management System
1.4. Responsibilities for the implementation of and maintenance of the Quality System Manual
1.5 Management representative
1.6 Quality Policy

2. Presentation of the organization

2.1. Localization
2.2. Brief History
2.3. Collaborators and infra-structures
2.4. Organigram
2.5 Function description

3. Organization of the Quality Management System

3.1 Types of Processes and responsibilities
3.2 Sequence and interaction of the processes
3.3 Inputs and outputs of the processes
3.4 Structure of the Quality Management System documentation
3.5 QMS 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, 6th July 2022

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 Vítor 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-existend knowledge in the research fields addressed by the Institute
- Clearly 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 on 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 to 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 EXPERTTISSUES 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 I3B’s - 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 3B’s in two sub-units:

  ➢ 3B’s Research Group
  ➢ 3B’s Innovation and Services

2.3. Collaborators and infrastructures

The Research Institute I3B’s, 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 I3B’s, and both Subunits.

The Institute I3B’s, 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. In addition, the Institute has a detailed communication plan (QR108) describing 1. What to communicate, 2. When to communicate, 3. To whom to communicate, 4. Who communicates, and 5. How is communicated. 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 customer.
- 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 below) 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

![Diagram showing the sequence and interaction of the processes]
### 3.3. Inputs and outputs of the processes

<table>
<thead>
<tr>
<th>Input source</th>
<th>Input</th>
<th>PROCESS</th>
<th>Designation</th>
<th>Responsible</th>
<th>Associated procedures</th>
<th>Output</th>
<th>Output destination</th>
</tr>
</thead>
</table>
| 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- Strategic management                                                                 | • 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- Service Execution Planning & Treatment and organization of Services and Consulting Request | • New EOP and/or MPRM and/or CRM 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 (IEC, CCDIN, 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- Management of Portfolio and R&D Projects & SOP012- Management of knowledge | Submitted project proposal  
  • Study plans (Q3R4)  
  • Information provided to financing entities  
  • QR36 | Financial entities (IEC, CCDIN, 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 Attitude Sheets|         | Human resources                    | President and Directors of both subunits | SOP004- Acceptance, training and check-out of researchers, SOP005- Human resources management & SOP004- Occupational Health, Safety and Environment Management | • Annual training plan (Q1R2)  
  • Training certificates (Q1R10)  
  • Monitoring of safety and health  
  • Air Monitoring  
  • Equipment Monitoring | All processes  
  • Equipment for research and services SOP011  
  • SOP001  
  • SOP005 |
| Need of new equipment | • New equipment acquired  
  • Equipment to react in external  
  • Performance of the equipment|         | Equipment                           | President and Directors of both subunits and Lab Manager | SOP013- Equipment Management                                                                 | • 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- Infrastructures and IT Management                                                                 | • 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 repetition  
  • Product supplies and technical information|         | Acquisitions                        | President and Directors of both subunits and Lab Manager | SOP008- Purchasing, evaluation and selection of suppliers                                                                 | • Consult/search to the supplier's market  
  • Orders confirmed to suppliers  
  • Products approved and available in the storage | SOP011  
  • SOP002  
  • SOP005 |
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.

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

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**3B's**

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### 3.4. Quality Management System Index

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Document/Record associated</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Context of the organization</td>
<td></td>
</tr>
<tr>
<td>4.1 Understanding the organization and its context</td>
<td>QM, QP, SOP003</td>
</tr>
<tr>
<td>4.2 Understanding the needs and expectations of interested parties</td>
<td>QM, QRB4, SOP003</td>
</tr>
<tr>
<td>4.3 Determining the scope of the quality management system</td>
<td>QM, QP, SOP003</td>
</tr>
<tr>
<td>4.4 Quality management system and its processes</td>
<td>QM, SOP003</td>
</tr>
<tr>
<td>5. Leadership</td>
<td></td>
</tr>
<tr>
<td>5.1 Leadership and commitment</td>
<td>QM, QRB6, SOP003, SOP005</td>
</tr>
<tr>
<td>5.2 Policy</td>
<td>All processes</td>
</tr>
<tr>
<td>5.3 Organization roles, responsibilities and authorities</td>
<td>QM, QP, SOP003, SOP005</td>
</tr>
<tr>
<td>6. Planning</td>
<td></td>
</tr>
<tr>
<td>6.1 Action to address risks and opportunities</td>
<td>All processes</td>
</tr>
<tr>
<td>6.2 Quality objectives and planning to achieve them</td>
<td>All processes</td>
</tr>
<tr>
<td>6.3 Planning of Changes</td>
<td>All processes</td>
</tr>
<tr>
<td>7. Support</td>
<td></td>
</tr>
<tr>
<td>7.1 Resources</td>
<td>All processes</td>
</tr>
<tr>
<td>7.2 Competence</td>
<td>SOP002, SOP005, SOP010, All processes</td>
</tr>
<tr>
<td>7.3 Awareness</td>
<td>All processes</td>
</tr>
<tr>
<td>7.4 Communication</td>
<td>SOP010, QP, SOP003</td>
</tr>
<tr>
<td>7.5 Documented information</td>
<td>QRB5, SOP001</td>
</tr>
<tr>
<td>8. Operation</td>
<td></td>
</tr>
<tr>
<td>8.1 Operational planning and control</td>
<td>SOP003</td>
</tr>
<tr>
<td>8.2 Requirements for products and services</td>
<td>SOP008, SOP010</td>
</tr>
<tr>
<td>8.3 Design and development of processes and services</td>
<td>SOP010, SOP011</td>
</tr>
<tr>
<td>8.4 Control of externally provided processes, products and services</td>
<td>QRB4, SOP008, SOP010</td>
</tr>
<tr>
<td>8.5 Production and service provision</td>
<td>SOP010, SOP011</td>
</tr>
<tr>
<td>8.6 Release of products and services</td>
<td>SOP010, SOP011</td>
</tr>
<tr>
<td>8.7 Control of nonconforming outputs</td>
<td>QRB6, SOP007</td>
</tr>
<tr>
<td>9. Performance Evaluation</td>
<td></td>
</tr>
<tr>
<td>9.1 Monitoring, measurement, analysis and evaluation</td>
<td>QRB4, QRB5</td>
</tr>
<tr>
<td>9.2 Internal Audit</td>
<td>QRB11, QRB4</td>
</tr>
<tr>
<td>9.3 Management review</td>
<td>QRB53, SOP003</td>
</tr>
<tr>
<td>10. Improvement</td>
<td></td>
</tr>
<tr>
<td>10.1 General</td>
<td>All processes</td>
</tr>
<tr>
<td>10.2 Nonconformity and corrective action</td>
<td>SOP007, QRB6</td>
</tr>
<tr>
<td>10.3 Continual Improvement</td>
<td>All processes</td>
</tr>
</tbody>
</table>

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