

**CONTACT DETAILS OF THE BODY SUBMITTING THE QUALIFICATION FILE**

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**List of documents submitted in support of the Qualifications File**

1. Annexure – I: Affiliation Norms
2. Annexure – II: IBSC Concept Note
3. Annexure – III: Model Curriculum
4. Annexure – IV: Letter from Industry to support the proposal
5. Annexure – V: Occupational Mapping & Skill Gap Study
6. Annexure – VI: Occupational Mapping Report
7. Annexure – VII: List of IBSC Partner Institutions

**SUMMARY**

<b>1</b>	<b>Qualification Title:</b>	Certificate in Biomedical Project Management
<b>2</b>	<b>Qualification Code, if any</b>	IBSC / BME / 05
<b>3</b>	<b>NCO code and occupation</b>	Bio-Medical Engineer – 2143.0200
<b>4</b>	<b>Nature and purpose of the qualification (Please specify the duration of the certificate validity)</b>	<p><b>Nature:</b> It is a Certificate Course in Biomedical Project Management</p> <p><b>Purpose:</b> The Certificate in Biomedical Project Management is a short duration skill-based training program, with an objective to develop a pool of trained workforce which can be employed by manufacturing industry / healthcare service providers. This program focuses on the acquisition of skills necessary to develop leadership skills required to the medical device industry.</p> <p>IBSC Skill Certification would certify bio-medical engineers &amp; technicians. The validity of the certificate is lifetime.</p>
<b>5</b>	<b>Body/bodies which will award the qualification</b>	Indian Bio Medical Skill Consortium (IBSC)
<b>6</b>	<b>Body which will accredit providers to offer courses leading to the qualification</b>	Quality Council of India (QCI)
<b>7</b>	<b>Whether accreditation/affiliation norms are already in place or not, if applicable (if yes, attach a copy)</b>	<p>Norms are in place for regulating the training centres and the assessment process.</p> <p>Affiliation norms are attached.</p> <p>Annexure - I</p>
<b>8</b>	<b>Occupation(s) to which the qualification gives access</b>	Project Manager
<b>9</b>	<b>Job description of the occupation</b>	The objective of the training program is to develop a pool of workforce which can be employed by focuses on the acquisition of

		<p>skills necessary to develop leadership skills as per medical device industry requirement.</p> <p>As per the training modules at the end of the training, the candidate would be certified to perform following activities -</p> <p>a) Quality Planning and Functions Throughout the Product Lifecycle, understand the peculiarities of different regulatory agencies and add greater burdens on new product development.</p> <p>b) The development of Medical Products by following rigid processes to ensure that a high quality, safe, and effective end product is built to meet customer requirements.</p> <p>c) Support in product manufacturing, fabricating component parts, delivering active pharmaceutical ingredients, consulting for clinical trials, regulatory, or project management, supplying product distribution networks, and storing medical data.</p> <p>d) Minimize the length of time from concept to market, number of studies, size and complexity of the clinical trials, and requirements for various countries' regulatory approvals are staggering.</p> <p>The detail progression is given in the item no 30 of this document.</p>
<b>10</b>	<b>Licensing requirements</b>	NOT applicable
<b>11</b>	<b>Statutory and Regulatory requirement of the relevant sector (documentary evidence to be provided)</b>	NOT applicable
<b>12</b>	<b>Level of the qualification in the NSQF</b>	Level – 7
<b>13</b>	<b>Anticipated volume of</b>	500 hours

	<b>training/learning required to complete the qualification</b>	
<b>14</b>	<b>Indicative list of training tools required to deliver this qualification</b>	<p>Syllabus, e-study materials, Sample question banks, Hands-on-workshops etc.</p> <p>List of tools and laboratories used to deliver this training program:</p> <ol style="list-style-type: none"> <li>1. Injection moulding machine</li> <li>2. Compression moulding machine</li> <li>3. Melting Point Apparatus</li> <li>4. MFI Tester (MFI Indexer)</li> <li>5. Muffle Furnace</li> <li>6. Chemical Testing Apparatus             <ol style="list-style-type: none"> <li>a) PH Meter</li> <li>b) Centrifuse</li> <li>c) Chemicals &amp; Glass works like burate, pippet, Pnecometer etc.</li> </ol> </li> <li>7. Density Gradient column</li> <li>8. Universal Testing Machine</li> </ol>
<b>15</b>	<b>Entry requirements and/or recommendations and minimum age</b>	<p>Minimum criteria:</p> <p>i) For Diploma candidates:            Diploma in biomedical / medical electronics / electrical / any other related filed., with 5 years of experience in biomedical field.</p> <p>ii) For Engineers:            B. E / B. Tech in Biomedical Engineering, Biomedical Instrumentation Engineering / Medical Electronics / any other related field, with 3 years of experience in biomedical field.</p>
<b>16</b>	<b>Progression from the qualification (Please show Professional and academic progression)</b>	<p><b>Professional Progression</b></p> <p>After the certification, the candidate will acquire specialized skills in the field of Project Management.</p> <p>Initially the candidate enters the profession as Executive, with this professional certificate candidate gets promoted to</p>

	<p>higher levels as Project Engineer, Project Manager, Senior Manager, General Manger, and Head.</p> <p><b>Academic Progression</b></p> <p>For diploma candidates they can entry directly to second year of engineering program in Bio-medical. Also, they can purse degree in distance mode.</p> <p>For engineering candidates, they can pursue M. Tech Biomedical or MBA. Also, they can pursue PG programme in distance mode.</p>
17	<p><b>Arrangements for the Recognition of Prior learning (RPL)</b></p> <p>When the individual has relevant experience, he is assessed through a Recognition of Prior Learning (RPL) programme.</p> <p>The candidate is assessed through a combination of theory test, practical knowledge and verbal questioning or VIVA.</p> <p>The test is designed by SME or Subject Matter Expert who prepares the test material with total integrity and objectivity.</p> <p>The candidate is administered a written test of 45 minutes and a practical test of 1.5 to 2 hours duration.</p> <p>Upon successful completion of the test the candidate is declared competent for yet to be competent, depending upon which the training is advised.</p> <p>The assessment is conducted by trained and qualified assessors appointed by IBSC. The tests are administered under strict confidentiality and absolute lack of bias or prejudice.</p>

		<p>For those with relevant years of experience in the medical device industry they can take direct assessment. In case if candidate couldn't qualify, he/she needs to under-take the training followed by assessment. However, it is recommended to the candidates to take required training before assessment.</p> <p>For those with less than relevant years of experience they should undergo training followed by assessment.</p> <p>For those with Diploma qualification need 5 years of relevant experience.          For those with Engineering qualification need 3 years of relevant experience.</p>
<b>18</b>	<b>International comparability (research evidence to be provided)</b>	<p>Association for the Advancement of Medical Instrumentation, USA (AAMI) &amp; American College of Clinical Engineering (ACCE), USA.          ACCE is a global leader in Medical Technology Certification (applicable worldwide). IBSC has signed MoU with ACCE for bilateral acceptance of practice.</p> <p>International documentation reviewed for the same included that following –</p> <p>IBSC forges global partnership with AAMI to certify biomedical engineering professionals  <a href="http://www.pharmabiz.com/NewsDetails.aspx?aid=110870&amp;sid=1">http://www.pharmabiz.com/NewsDetails.aspx?aid=110870&amp;sid=1</a>          IBSC inks pact with AAMI  <a href="https://www.biospectrumindia.com/news/74/11546/ibsc-inks-pact-with-aami.html">https://www.biospectrumindia.com/news/74/11546/ibsc-inks-pact-with-aami.html</a></p>
<b>19</b>	<b>Date of planned review of the qualification.</b>	<p>It is proposed that the qualification to be reviewed every three years.          *from the date of clearance of the Qualification</p>
<b>20</b>	<b>Formal structure of the qualification Mandatory components</b>	

	<b>Project Manage (Engineer / Technologist)</b>		
	70 % of the teaching hours will be practical / videos & presentation, demonstrations and 30% will be theory.		
(i)	<b>Title of component and identification code/NOSs/Learning outcomes</b>	<b>Estimated size (learning hours)</b>	<b>Level</b>
	Course Code	Name of the Module	
	PM01	Basic concepts & Application of Project Management	100
	PM02	Project Modelling and Management with Applications in MS – Project	100
	PM03	People Management in Projects	75
	PM04	Scope Management	75
	PM05	Applying Project Management Principles to Biomedical Industry	150
		<b>Sub Total</b>	<b>500</b>
			<b>7</b>

**SECTION 1**  
**ASSESSMENT**

<b>21</b>	<p><b>Body/Bodies which will carry out assessment:</b></p> <p>M/s MeritTrac Testing Services, Bangalore has been selected through bidding and shall conduct the online assessment test across India. Indian Bio-Medical Skill Consortium, AMTZ Campus, Visakhapatnam shall develop the content of assessment.</p>
<b>22</b>	<p><b>How will RPL assessment be managed and who will carry it out?</b></p> <p>IBSC conducts QP-NOS based direct three-way assessment for each and every candidate applied for recognition of prior learning (vis. Certifying the un-certified but skilled workforce who acquired skills through years of experience. Here, the candidates may undergo short-term training of gaps identified.</p> <p><b>1) Registration:</b>  The candidates need to submit registration form online along with uploading of scanned copies of some mandatory documents (work experiences). The applications will be screened on the basis of the eligibility criteria and approved candidates will be dully informed.</p>

	<p><b>2) Pre-Assessment:</b></p> <p>The candidates who has relevant experience, he is assessed through a Recognition of Prior Learning (RPL) programme. The candidate is assessed through a combination of theory test, practical knowledge and verbal questioning or VIVA. The test is designed by SME or Subject Matter Expert who prepares the test material with total integrity and objectivity. The candidate is administered a written test of 45 minutes and a practical test of 1.5 to 2 hours duration. Upon successful completion of the test the candidate is declared competent for yet to be competent, depending upon which the training is advised. The assessment is conducted by trained and qualified assessors appointed by IBSC. The tests are administered under strict confidentiality and absolute lack of bias or prejudice. Those who score more than 80% they can directly appear for final assessment. Those who score less than 80% they should undergo skill training program.</p> <p><b>3) Final Assessment:</b></p> <p>The shortlisted candidates from pre-assessment are finally selected for final assessment. The assessment is conducted by Indian Biomedical Skill Consortium (IBSC).</p>
23	<p><b>Describe the overall assessment strategy and specific arrangements which have been put in place to ensure that assessment is always valid, reliable and fair and show that these are in line with the requirements of the NSQF.</b></p> <p>The process of assessment followed ensures that the assessment is strictly in accordance to the qualification pack, the NOS and PCs mentioned. Validity depends upon how well the assessment actually measures the learning outcome. The test is prepared against the assessment criteria set by the IBSC, which has in turn identified the core skills and the supplementary skills in terms of NOS and PC. That the test is designed according to the assessment criteria and is prepared by subject matter experts who are established in their fields ensures the validity of the test.</p> <p>Consistency of the test is dependent on the fact that the assessment generates consistent results inspite of change in evaluators, location etc. The MCQ pattern followed for the theory rules out any element of prejudice or subjectivity on the part of the evaluator. The practical is designed in such a manner that the core skills and supplementary skills are tested and evaluated. The trained assessors who are experts in the field ensure that the test is consistent. Fairness is ensured as the students are given equal opportunity irrespective of their religion, social back ground or gender. The roll numbers assigned to the candidates conceal their identity and making the evaluation impartial.</p>



**Assessment Guidelines:**

1. The criteria for assessment is based on module/s for which the candidate has enrolled out of the total course modules.
2. The individual modules are mapped with specialized skill in the area of Healthcare Technology.
3. Individual module carries equal weightage and marks.
4. The outcome of the learning process is based on best practices adopted in Healthcare Technology.

**The Assessment Parameters adopted during assessment:**

- 1) Knowledge of equipment, limitation of use of tools and equipment, and methods & procedure.
- 2) Understanding of functioning of equipment & tool, criteria to be used in selecting tools for given
- 3) job, and the process of measurement.
- 4) Skill in finishing to required measurement, handling measurement & calculations, handling tools
- 5) and equipment with ease, finishing neatly.
- 6) Abilities to take corrective steps, use correct work habits, take measurements, complete the job
- 7) within stipulated time, and adopt safe practices.
- 8) Attitude towards the work, accurate & precise work and co-workers and supervisor.

**Theory Test / Internal Assessment:**

- 1) The questions shall be normally of objective type involving selection of correct response rather than writing sentences.
- 2) The question paper shall contain sketches/ diagrams/ photographs/ drawing to overcome the problems of reading comprehension.
- 3) The test shall be of short duration.

**Practical Test / Viva-voice:**

It shall be able to test:

- 1) Manipulative skills to handle tools and equipment.
- 2) Speed in doing work.
- 3) Accuracy maintained
- 4) Quality in workmanship.
- 5) Sequence of performance.
- 6) Economical use of material.
- 7) All the competencies prescribed in the course curriculum.

**Testing & Certification Process:**

**Application Process:**

1. The candidate enrolls for the modules for assessment.
2. IBSC would declare a specific period for registration for assessment.
3. Applicant will fill the details along with supporting documents.
4. The uploaded documents will be verified & approved by IBSC.
5. Applicant can book the online examination centre as per the requirement.
6. After the online examination, IBSC will prepare the certification based on online test marks.
7. The verification & approval section will be recommended for the final certification.
8. The applicant will be communicated by Email & SMS about award of certificate.

**Assessment Process:**

1. Candidate should reach the venue 45 minutes before the start of the test.
2. Candidates should carry valid training ID card or else an ID card approved by the Government of India (PAN Card, Aadhar Card, DL, etc).
3. Candidates without any identification are not allowed to take the test.

**Candidates should follow these guidelines:**

- a) No usage of electronic devices (mobiles and calculators) during the test
- b) No malpractice during the test hours
- c) Talking is not allowed during the test
- d) There are 30 (Varies for different QPs) multiple choice questions
- e) Each question has only one correct answer
- f) There is no negative marking
- g) Candidates need to attempt all questions to complete the test.
- h) Pencil, eraser, and white paper will be provided to all the candidates.

**Examination Procedure:**

- 1) Mode of Application: Online
- 2) Examination Pattern: Objective
- 3) Total number of Modules: 5
- 4) Number of questions in each module: 30
- 5) Time duration for examination of one module: 90 minutes

**Qualifying Criteria:**

- 1) Minimum 60% in each module is required to qualify the exam.
- 2) If any candidate has not qualified any module/s s/he can take re-exam

	<p>in that module/s.</p> <p><b>Post-assessment activities</b></p> <ol style="list-style-type: none"> <li>1) The testing partner shall share the consolidated report (attendance sheet, results sheet) to the IBSC immediately after the completion of assessment.</li> <li>2) IBSC will verify each application and approve the test scores.</li> <li>3) Uploading outcome of the assessment and photos in portal by IBSC.</li> <li>4) IBSC upload the results within one week of the assessment date.</li> <li>5) IBSC shall maintain assessment records.</li> <li>6) Publishing of results and Certificate issue</li> <li>7) Certificates which will be issued carry QR code, qualified modules, technology competency score.</li> <li>8) The certificate is issues under the aegis of NSDC and partner affiliations.</li> </ol> <p><b>Direct Assessment:</b></p> <ol style="list-style-type: none"> <li>1) Candidates desire to get the skills certified have to apply online.</li> <li>2) IBSC would declare a specific period for registration for assessment.</li> <li>3) Applicant will fill the details along with supporting documents.</li> <li>4) The uploaded documents will be verified &amp; approved by IBSC.</li> <li>5) Applicant can book the online examination centre as per the requirement.</li> <li>6) After the online examination, IBSC will prepare the certification based on online test marks.</li> <li>7) The verification &amp; approval section will be recommended for the final certification.</li> <li>8) The applicant will be communicated by Email &amp; SMS about award of certificate.</li> </ol>
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**24. Assessment evidences**

**Title of Component: Certificate in Biomedical Project Management**

	<b>Compulsory NOS</b>				<b>Marks Allocated</b>
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Outcomes to be assessed / NOSs to be assessed	Assessment criteria for the outcome	Total	Out of	Viva-voice	Total
IBSC / BME / PM01 Basic concepts & Application of Project Management	PC1. Understand the overall medical device product development Stage-Gate process.	<b>25</b>	5	2	3
	PC2. Able to demonstrate and familiar with common terminology used for industry.		5	2	3
	PC3. Demonstrate the skills to manage large development project, and common management systems deployed (i.e., portfolio management and stage gate product processes).		5	2	3
	PC4. Acquire knowledge to utilize some of the best project management processes to plan, execute, and control their products.		5	2	3
	PC5. Understand all the inputs, tools and techniques, and outputs for each project management process.		5	2	3
		<b>Total</b>	<b>25</b>	<b>10</b>	<b>15</b>
IBSC / BME / PM02 Project Modelling and Management with Applications in MS – Project	PC1. Ability to initiate, plan, execute, monitor and control a medical device product development project.	<b>25</b>	5	2	3

	PC2. Demonstrate and define project work to an appropriate level of detail.		5	2	3
	PC3. Demonstrate and identify appropriate technologies in project modelling.		5	2	3
	PC4. Designing processes and methods that align with the standard template and outfitting Model.		5	2	3
	PC5. Distinguish and apply quality planning, assurance, and control methods		5	2	3
		<b>Total</b>	<b>25</b>	<b>10</b>	<b>15</b>
IBSC / BME / PM03 People Management in Projects	PC1. Ability to communicate more effectively with the people they work with for achieving outcomes.	<b>25</b>	5	2	3
	PC2. Demonstrate the communication skills and facilitating decision-making among stakeholders		5	2	3
	PC3. Performance manage to facilitate growth and enable effective corrective action where needed.		5	2	3
	PC4. Communicating and coordinating with next-higher level of management on project.		5	2	3

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	PC5. Ability to deliver leadership style and communication skills when managing others.		5	2	3
		<b>Total</b>	<b>25</b>	<b>10</b>	<b>15</b>
IBSC / BME / PM04 Scope Management	PC1. Candidate should be able to understand project scope management, detect variances from the scope baseline and recommend corrective actions.	<b>25</b>	5	2	3
	PC2. Understand what is needed for a comprehensive project plan.		5	2	3
	PC3. Understand the roles of a project manager, sponsor(s), and core team		5	2	3
	PC4. Determine metrics for a project requirement to meet the business need for the project.		5	2	3
	PC5. Demonstrate the needs of project objectives, and ability to creation of a detail project scope statement.		5	2	3
		<b>Total</b>	<b>25</b>	<b>10</b>	<b>15</b>
IBSC / BME / PM05 Applying Project Management Principles to	PC1. Demonstrate and manage the challenges of a medical device project.	<b>25</b>	5	2	3

Biomedical Industry	PC2. Define and identify project risks and ways to mitigate these risks.		5	2	3
	PC3. Identify risks using both qualitative and quantitative methods		5	2	3
	PC4. Demonstrate the skills by Implementing large-scale systems in a project-management role.		5	2	3
	PC5. Ability to maintain product documentation, design history files, product safety records, and quality records requires companies to complete compliance projects to meet the standards.		5	2	3
		<b>Total</b>	<b>25</b>	<b>10</b>	<b>15</b>
		<b>Grand Total</b>	<b>125</b>	<b>50</b>	<b>75</b>
<p><b>Practical &amp; Skill Test (pre-assessment)</b>            After the completion of sufficient training hours, the candidates should maintain 75% of attendance. The candidates should qualify the pre-assessment test consists of both theory &amp; skill test. Those who qualified in pre-assessment test with 75% they will be shortlisted for final assessment. Those who not qualified in pre-assessment they should reappear in the pre-assessment test.</p>					
<p><b>Theory Assessment (final)</b>            In the final assessment it consists of 30 questions in each module to evaluate the competency of the candidate.</p>					
<p><b>Pass/Fail:</b>            The minimum criteria for passing in final assessment is 60% in each module.</p>					

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**SECTION 2**

**25. EVIDENCE OF LEVEL**

<b>Title/Name of qualification/component: Project Manager</b>			<b>Level: 7</b>
<b>NSQF Domain</b>	<b>Outcomes of the Qualification/Component</b>	<b>How the outcomes relate to the NSQF level descriptors</b>	<b>NSQF Level</b>
Process	The candidates should support in product manufacturing, fabricating component parts, consulting for clinical trials, regulatory, project management supplying product distribution networks and storing data. The candidate should be familiar with quality planning and functions throughout the product lifecycle, understand the peculiarities of different regulatory agencies and add greater value to new product development.	The candidate should demonstrate the principles of project management, standards and processes to the organization development to ensure that the high quality, safe and effective end-products is built to meet customer requirements. Hence it is mapped with level - 7.	7
Professional knowledge	The candidates should able to understand the complexity of the technologies, an increasing need for cross-disciplinary works, and rapid scientific advancements and design new models. They should also have ability to understand and define project requirements and required resources, including capabilities, knowledge and skills for the necessary works, cost requirements and risks involved. They should have ability to integrate processes by utilizing best project management practices to plan, execute and control the products.	The candidates should demonstrate the cross-disciplinary functions by utilizing electronics, miniaturization, fluidics, robotics and computers to produce new products. They should maintain collection of massive amounts of information permitted for both the improvement of medical technologies and the creation of knowledge necessary to make further improvements. Hence it is mapped with level – 7.	7
Professional skill	The job holder involves with multiple activities where project management takes a leadership role due to cross-functional	The candidates should be able to introduce additional processes in monitoring and	7

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<b>Title/Name of qualification/component: Project Manager</b>			<b>Level: 7</b>
<b>NSQF Domain</b>	<b>Outcomes of the Qualification/Component</b>	<b>How the outcomes relate to the NSQF level descriptors</b>	<b>NSQF Level</b>
	inputs required for activities, communication, team management, and follow through on completing deliverables. They should also ability to prepare and manage the documents, monitor the achievement of the product requirements, and ensure the clinical materials meet the design requirements.	controlling requirements, reducing the variation of components parts and products, enhancing supplier quality, improving testing methods and technologies, and increasing the emphasis on quality as means of improving customer satisfaction and loyalty. Hence it is mapped with level - 7.	
Core skill	The job holder should demonstrate the project management concepts to address challenges, such as faster development cycles, mistake reduction, rapid technology change, international competition, quality issues, and cost containment. They should perform leadership roles and deliver instructions to technical staff directing the operations and meet the expected deliverables.	The candidates should able to identify the risk and ability to create a plan to mitigate the change for risk. They should be able to lead a cohesive team and direct them on project towards a successful conclusion. Hence it is mapped with level – 7.	7
Responsibility	The job holder is responsible for end to end manufacturing process including, determining project process, establishing project team, and ensuring understanding of roles and responsibilities. Monitoring team performance and intervene when necessary to ensure successful delivery. Establish and monitor project schedule and ensure routine updates and reporting to the higher authority. They should also able to develop proposal, negotiate contracts, contract selection, monitor contract performance and ensure delivery of	Able to maintain product documentation, design history files, keep a tract of product safety records, and quality records to complete compliance projects to meet the standards. Hence it is mapped with Level – 7.	7

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<b>Title/Name of qualification/component: Project Manager</b>			<b>Level: 7</b>
<b>NSQF Domain</b>	<b>Outcomes of the Qualification/Component</b>	<b>How the outcomes relate to the NSQF level descriptors</b>	<b>NSQF Level</b>
	services.		

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**SECTION 3**  
**EVIDENCE OF NEED**

<b>26 Is this certification made mandatory by any statutory body?</b>		
<b>Basis</b>	<b>Description</b>	<b>Evidence</b>
Need of the qualification	The IBSC would undertake market study and would enclose demand forecast for the proposed job role both on short-term and long-term basis to substantiate the requirement of the job role.	<p>The Global medical device industry is poised to reach USD 543.9 Billion by 2020 driven by the increase in the lifespan of aging individuals as well as the increasing costs of healthcare globally. The Indian medical device market is currently established at USD 5.5 Billion and is growing yearly at a steady rate of 15% CARG. A rise in the number of hospitals and the increased requirement for healthcare facilities creates a need for sophisticated devices and equipment, which can provide accurate treatment to individuals. It is expected that the Medical Equipment industry will need at least 1.0 lakh trained professionals every year and this number is likely to increase in the near future.</p> <p>Skill Gap Analysis reports for industry demand and secondary research data, though these do not lend to accurate demand projection.</p> <p>Occupation map is attached ANNEXURE – V &amp; VI</p>
Industry Relevance	The IBSC would undertake validation of the job roles with actual end-user	As per the detailed survey done by Ministry of Health &

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		<p>industry where such employment are going to be generated and absorbed instead of generic validation of industry. The IBSC would submit the endorsements from users/ intended users of the qualification clearly supporting or otherwise the need for trained people against specific job role. The industry validation report is attached. ANNEXURE - IV</p>	<p>Family welfare, it is found that in India there are only 3.32 biomedical engineers per 1,00,000 population. Ministry has already urged the industry bodies and government to share the road map for biomedical engineering to take control of healthcare industry.</p> <p>The report also indicates that 60% of the medical equipments in government institutions are in an unserviceable condition due to lack of maintenance. Hence rigorous training along with strong knowledge has to be imparted to these professionals.</p> <p>Hence this certification paves the way for having a system in place for recognising the skills of biomedical engineers &amp; apply their skills in their profession backed by a certificate.</p> <p>Feedback from industry for demand though sample size may not lend to accurate figures. Training duration, and current and potential training capacity envisaged. The Qualification Pack has been validated by the industry along with endorsements and also received validation from Association of Indian Medical Device Industry (AiMeD)</p>
Usage of the qualification		The IBSC would submit details of the employment generated (wherever	The Medical Equipment industry is the fastest growing sector of the Indian economy and the need for trained

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**Approved in 23<sup>rd</sup> NSQC, 22<sup>nd</sup> August, 2019**

	<p>applicable) and realised by virtue of training in the Qualifications of the sector earlier submitted for NSQF alignment.</p>	<p>manpower is growing. The trained candidates will be employed in hospitals, medical equipment service company, medical device manufacturing industry and etc.</p>
<p>Estimated uptake</p>	<p>The IBSC would submit the estimated uptake of the qualification and What steps were carried out to test the likely uptake of the qualification. The basis of this estimate should include data about the number of jobs or places in courses of learning which will be available to the candidates.</p>	<p>As per the Healthcare sector report, workforce requirements for the Healthcare sector is expected to grow to 74 lakhs in 2022 which is more than double its existing workforce to meet the market demand. Additionally, the major percentage of the requirement is of allied and healthcare professionals (A&amp;HP) apart from nursing and medical doctors. It is essential to also realign the existing workforce with the required course, so that their skills can be tested and adequate knowledge and skills can be rendered for them to be called as a qualified Biomedical Engineer.</p> <p>Report: Human resource and skill requirement in Health sector is available at  <a href="https://www.ugc.ac.in/skill/SectorReport/Healthcare.pdf">https://www.ugc.ac.in/skill/SectorReport/Healthcare.pdf</a></p>

NSQC Approved

27	<p><b>Recommendation from the concerned Line Ministry of the Government / Regulatory Body. To be supported by documentary evidences</b></p> <p>Department of Health &amp; Family Welfare</p>
28	<p><b>What steps were taken to ensure that the qualification(s) does (do) not duplicate already existing or planned qualifications in the NSQF? Give justification for presenting a duplicate qualification</b></p> <p>Sufficient research has been done to establish that the certificate course is not available for the skill development of the candidates in Biomedical Sector under the existing Sector Skill Council.</p> <p>The Certification has been mapped with the National Qualification Register, maintained by NSDA to ensure that the qualification does not duplicate. The Certification program is originally designed by core groups including Technical committee, certification committee &amp; strategic committee. These committees are comprising of senior biomedical engineers, industrial experts and experienced academicians.</p>
29	<p><b>What arrangements are in place to monitor and review the qualification(s)? What data will be used and at what point will the qualification(s) be revised or updated? Specify the review process here</b></p> <ul style="list-style-type: none"> <li>i. IBSC office monitors the screened candidates periodically as per the module.</li> <li>ii. The review report generated on the basis of previous response by the candidates &amp; benefits candidate on the professional front.</li> <li>iii. The technical committee will be informed to revise the syllabus &amp; question bank for continuous improvements.</li> <li>iv. Qualification is reviewed after every three years for updating according to latest technologies &amp; practices.</li> </ul>

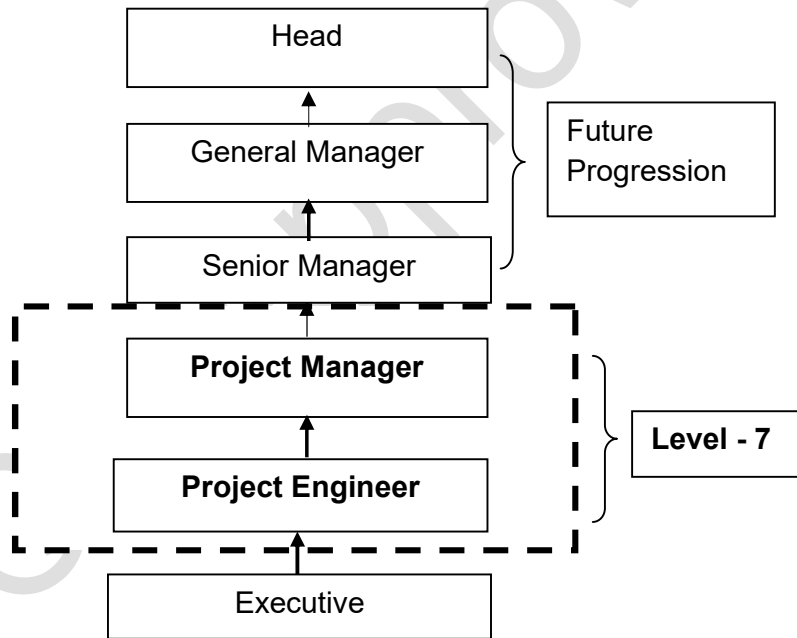
**SECTION 4**  
**EVIDENCE OF PROGRESSION**

30	<p><b>What steps have been taken in the design of this or other qualifications to ensure that there is a clear path to other qualifications in this sector?</b></p>
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**Show the career map here to reflect the clear progression**

The Certification program designed for “Certificate in Biomedical Project Management”, is shown below. This certification programme screens potential candidates based on basic knowledge, skill and ability in different domains of Healthcare Technology for achieving the higher level. Also, scope is further extended to adopt the progress & advancements in the syllabus of the module/s. This will help employer to source Industry-ready professionals (depending on the specialization needs of the job). The validity of the certificate is 3 years & lays further scope in continuous improvement in the interested areas.

**Certificate in Biomedical Project Management – Career Graph**



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