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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

1	**Qualification Title:**	Certificate in Biomedical Quality Assurance
2	**Qualification Code, if any**	IBSC / BME / 04
3	**NCO code and occupation**	Bio-Medical Engineer – 2143.0200
4	**Nature and purpose of the qualification (Please specify the duration of the certificate validity)**	**Nature:** It is a Certificate course in Biomedical Engineering **Purpose:** The "Certificate in Biomedical Quality Assurance" is a short duration skill-based training program, with an objective to develop a pool of trained workforce which can employed by manufacturing industry / healthcare service providers. This program focuses on the acquisition of skills necessary to develop quality control of medical devices and validation process. IBSC Skill Certification would certify skilled and experienced bio-medical engineers & technicians. The validity of the certificate is lifetime.
5	**Body/bodies which will award the qualification**	Indian Bio Medical Skill Consortium (IBSC)
6	**Body which will accredit providers to offer courses leading to the qualification**	Quality Council of India (QCI)
7	**Whether accreditation/affiliation norms are already in place or not, if applicable (if yes, attach a copy)**	Norms are in place for regulating the training centers and the assessment process. Affiliation norms are attached. Annexure - I
8	**Occupation(s) to which the qualification gives access**	Quality Manager
9	**Job description of the occupation**	The objective of the training program is to develop a pool of workforce which can be employed by focuses on the acquisition of skills necessary to develop quality control

		of medical devices and validation process. As per the training modules at the end of the training, the candidate would be certified to perform following activities - a) Works cooperatively with R&D, Process Development, Quality, Production, Regulatory, Equipment Engineering, Supply Chain, and Marketing to ensure project success. b) Prepares standard reports/ documentation to communicate results to the technical community. c) Responsible for developing appropriate test methods and inspection plans. Test methods shall be validated as necessary. d) Ensures quality products are developed in accordance to governing regulations and processes. e) Actively participate and assist teams with Risk Analysis to include Risk Assessments. f) Responsible for product change assessments, health hazard evaluations and product recall documentation.
10	**Licensing requirements**	NOT applicable
11	**Statutory and Regulatory requirement of the relevant sector (documentary evidence to be provided)**	NOT applicable
12	**Level of the qualification in the NSQF**	Level – 6
13	**Anticipated volume of training/learning required to complete the qualification**	500 hours
14	**Indicative list of training tools**	Syllabus, e-study materials, Sample

	required to deliver this qualification	question banks, Hands-on-workshops etc. **List of Tools & Instruments** 1. Measure Tape 2. Outside, inside spring calliper 3. Spring divider 4. Try square 5. Combination plier 6. Cutting plier 7. Screwdriver 15 cm 8. Screwdriver set 9. D/E spanner set inch & mm 10. Allen key set inch & mm 11. Pipe wrench 12. Adjustable spanner 13. Hand Hacksaw frame adjustable 14. Hacksaw Blades 15. Bench vice with working table 16. Portable Hand drill 0-6mm with drill bits 17. Centre punch 18. Chisel 19. Flat file second cut & smooth 20. Half round file second cut & smooth 21. Needle file rough & smooth 22. Ball peen hammers 23. Plastic hammer (Soft) 24. Mould Clamping Block 25. Micrometre 0-25 mm 26. Vernier calliper 27. Thickness gauge 28. Electric line Tester 29. Multi meter 30. Test lamp **List of Machinery & Equipment** 1. Injection moulding machine 2. Compression moulding machine 3. Melting Point Apparatus 4. MFI Tester (MFI Indexer) 5. Muffle Furnace

		6. Chemical Testing Apparatus a) PH Meter b) Centrifuse c) Chemicals & Glass works like burate, pippet, Pnecometer etc. 7. Density Gradient column 8. Universal Testing Machine
15	**Entry requirements and/or recommendations and minimum age**	**Minimum criteria:** **i) For Diploma candidates:** Diploma in biomedical / medical electronics / electrical / any other related filed. With 3 years of experience in biomedical field. **ii) For Engineers:** B. E / B. Tech in Biomedical Engineering, Biomedical Instrumentation Engineering / Medical Electronics / any other related field, with 2 years of experience in biomedical field. Candidates who qualified related IBSC modules and approved by IBSC are exempted to take the training on modules. Upon the registration to the training program the certificate will be issued to such candidates.
16	**Progression from the qualification (Please show Professional and academic progression)**	**Professional Progression** After the certification, the candidate will acquire specialized skills in the field of Quality Management. Initially the candidate enters the profession as Coordinator, with this professional certificate candidate gets promoted to higher levels as Quality Control Engineer, Quality Manager, Quality Assurance Manager and Quality Assurance Director. **Academic Progression**

		For diploma candidates they can entry directly to second year of engineering program in Bio-medical. Also, they can purse degree in distance mode. For engineering candidates, they can pursue M. Tech Biomedical or MBA in Hospital Administration. Also, they can pursue PG programme in distance mode.
17	**Arrangements for the Recognition of Prior learning (RPL)**	When the individual 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.
18	**International comparability (research evidence to be provided)**	Association for the Advancement of Medical Instrumentation, USA (AAMI) & American College of Clinical Engineering (ACCE), USA. ACCE is a global leader in Medical Technology Certification (applicable world-wide). IBSC has signed MoU with ACCE

		for bilateral acceptance of practice. International documentation reviewed for the same included that following – IBSC forges global partnership with AAMI to certify biomedical engineering professionals http://www.pharmabiz.com/NewsDetails.aspx?aid=110870&sid=1 IBSC inks pact with AAMI https://www.biospectrumindia.com/news/74/11546/ibsc-inks-pact-with-aami.html
19	**Date of planned review of the qualification.**	It is proposed that the qualification to be reviewed every three years. *from the date of clearance of the Qualification
20	**Formal structure of the qualification: Quality Manager** **70 % of the teaching hours will be practical / videos & presentation, demonstrations and 30% will be theory.**	

	Title of component and identification code/NOSs/Learning outcomes		**Estimated size (learning hours)**	**Level**
	Course Code	Name of the Module		
	QM01	Medical Device Quality and Regulatory Fundamentals	125	6
	QM02	Risk Management & Risk Analysis	50	6
	QM03	Medical Technology Quality Systems	125	6
	QM04	Design Control & Product Development	100	6
	QM05	Design Verification, Validation, Clinical evaluation and CAPA	100	6
		Sub Total	**500**	**6**

SECTION 1
ASSESSMENT

21	**Body/Bodies which will carry out assessment:** 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 (IBSC), AMTZ Campus, Visakhapatnam shall develop the content of assessment.
22	**How will RPL assessment be managed and who will carry it out?** 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. **1) Registration:** 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. **2) Pre-Assessment:** 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 that 80% they can directly appear for final assessment. Those who score less than 80% they should undergo skill training program. **3) Final Assessment:** The shortlisted candidates from pre-assessment are finally selected for final assessment. The assessment is conducted by Indian Biomedical Skill Consortium (IBSC).
23	**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.

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.

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.

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 enrols 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 in that module/s.

Post-assessment activities

1) The testing partner shall share the consolidated report (attendance sheet, results sheet) to the IBSC immediately after the completion of assessment.
2) IBSC will verify each application and approve the test scores.
3) Uploading outcome of the assessment and photos in portal by IBSC.
4) IBSC upload the results within one week of the assessment date.
5) IBSC shall maintain assessment records.
6) Publishing of results and Certificate issue
7) Certificates which will be issued carry QR code, qualified modules, technology competency score.
8) The certificate is issues under the aegis of NSDC and partner affiliations.

Direct Assessment:

1) Candidates desire to get the skills certified have to apply online.
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. The applicant will be communicated by Email & SMS about award of certificate.

24. Assessment evidences
Title of Component: Quality Manager

	Compulsory NOS			Marks Allocated	
Outcomes to be assessed/NOSs to be assessed	**Assessment criteria for the outcome**	**Total**	**Out of**	**Viva-voice**	**Pract-ical**
IBSC / BME / QM01 Medical Device Quality and Regulatory Fundamentals	PC1. Describe the quality, development of process flow chart of quality management, and regulations.	**30**	5	2	3
	PC2. Define an appropriate regulatory pathway for a number of device classifications and associated conformity assessment routes.		5	2	3
	PC3. Demonstration the quality systems and standards.		5	2	3
	PC4. Ability to design and develop the quality process flow chart and regulations		5	2	3
	PC5. Identify the key documents required in technical documentation to support an regulatory submission.		5	2	3
	PC6. Demonstrate the role and expectations of the manufacturer, authorized representative, notified body and Competent Authority.		5	2	3
		Total	**30**	**12**	**18**
IBSC / BME / QM02 Risk Management & Risk Analysis	PC1. Describe the concept of Risk Management	**30**	5	2	3
	PC2. Describe a basic Risk management system and its components		5	2	3
	PC3. Describe the risk management process to other processes.		5	2	3

	PC4. Describe how risk management is linked to other quality management related process.		5	2	3
	PC5. Describe the effectiveness of the risk management process and quality management systems.		5	2	3
	PC6. Describe the risk management tools used to help manage risk in the product lifecycle		5	2	3
		Total	**30**	**12**	**18**
IBSC / BME / QM03 Medical Technology Quality Systems	PC1. Understand the industry-specific needs in quality assurance and present the regulatory and quality standards that are required for the medical device industry.	**15**	5	2	3
	PC2. Candidate should be able to evaluate the quality system as it conforms to regulatory requirements.		5	2	3
	PC3. Candidates also able to identify medical device-related risk assessment and evaluation, integration of medical device manufacturing strategies, using quality audition tools and techniques.		5	2	3
		Total	**15**	**6**	**9**
IBSC / BME / QM04 Design Control & Product Development	PC1. Implement the various development and manufacturing steps involved in product development process.	**10**	5	2	3
	PC2. Candidate should be able to maintain documents related to product development process to prove the device is safe and effective.		5	2	3

		Total	**10**	**4**	**6**
IBSC / BME / QM05 Design Verification, Validation, Clinical evaluation and CAPA	PC1. Understand the context of validation, verification and clinical evaluation.	**15**	5	2	3
	PC2. Candidate should be able to differentiate validation and verification, need of validation, verification and clinical evaluation procedures.		5	2	3
	PC3. Candidates should develop protocol template for V & V. Candidate should be able to understand Corrective Action and Preventive Action (CAPA).		5	2	3
		Total	**15**	**6**	**9**
		Total	**100**	**40**	**60**

Practical & Skill Test (pre-assessment)
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 & 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.

Theory Assessment (final)
In the final assessment it consists of 30 questions in each module to evaluate the competency of the candidate.

Pass/Fail:
The minimum criteria for passing in final assessment is 60% in each module.

SECTION 2

25. EVIDENCE OF LEVEL

Title/Name of qualification/component: Quality Manager			**Level:** 6
NSQF Domain	**Outcomes of the Qualification/Component**	**How the outcomes relate to the NSQF level descriptors**	**NSQF Level**
Process	The candidate will be familiar with definitions of quality systems, standards, verification and validation. Also, should be able to develop profess flow chart of quality management for the organization. They will work closely with various departments including R & D, Process Development, Production, Regulatory, Equipment Supply Chain, and Marketing.	The candidate should able to chart the evolution of quality management and process, understand the definitions of quality and aware of the various quality management tools and systems. With the design of quality process flow charts the eminence output can be expected. Hence it is mapped with level-6.	6
Professional knowledge	The job requires individuals to work in a team and in close collaboration with quality, production and research. They must be able to Implement the new developments, validation and manufacturing steps to the extended lifecycles of Medical devices.	The Applicants are screened as per their professional knowledge in Quality Management. This includes understanding the possible future development for quality management. Hence it is mapped with level – 6.	6
Professional skill	The quality managers should understand measurement limitations in accuracy and repeatability and accurately representing the data. They should be effective use of data analysis tools and also problem-solving skills. They should also able to effectively interact	The applications are screened on their skills in delivering their duties including how to manage and execute the given multiple tasks, their coordination with the other departmental staff. Hence it is mapped with level - 6.	6

Title/Name of qualification/component: Quality Manager			**Level:** 6
NSQF Domain	**Outcomes of the Qualification/Component**	**How the outcomes relate to the NSQF level descriptors**	**NSQF Level**
	with internal departments, external customers and suppliers. They should have positive attitude and willing to learn new methods and systems. The candidates should be able to balance and effectively manage multiple tasks and goals.		
Core skill	The candidate should be updated with latest quality standards, validation and verification processes. They should be able to understand and review quality assurance specifications and technical drawings required for the expectations of new devices. They should be able to understand the risk management process in correlation with other processes.	The Applicants are certified based on core skills like being resourceful & adopting best practices in manufacturing of medical devices. Candidate should be able to gain in depth understanding of how risk management is linked to other quality management related process. Hence it is mapped with level – 6.	6
Responsibility	The candidates should have responsibility of quality assurance function in the medical device industry. They should be able to implement quality standards and systems, extending the lifecycle of medical devices by best practicing of Good Manufacturing, Laboratory and Clinical practices. Maintaining documents including regulations and standards.	The candidates should demonstrate how Good Manufacturing, Laboratory and Clinical Practices can facilitate to the product. They should also be able to choose the right testing facility and achieve cost-effective manufacturing process. Hence it is mapped with Level - 6	6

SECTION 3
EVIDENCE OF NEED

26 **Is this certification made mandatory by any statutory body?**

Basis	Description	Evidence
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.	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. Skill Gap Analysis reports for industry demand and secondary research data, though these do no lend to accurate demand projection. Occupation map is attached ANNEXURE – V & VI
Industry Relevance	The IBSC would undertake validation of	

	the job roles with actual end-user 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	As per the detailed survey done by Ministry of Health & 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. 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. Hence this certification paves the way for having a system in place for recognising the skills of biomedical engineers & apply their skills in their profession backed by a certificate. 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)
Usage of the	The IBSC would submit details of the	The Medical Equipment industry is the fastest growing

qualification	employment generated (wherever applicable) and realised by virtue of training in the Qualifications of the sector earlier submitted for NSQF alignment.	sector of the Indian economy and the need for trained manpower is growing. The trained candidates will be employed in hospitals, medical equipment service company, medical device manufacturing industry and etc.
Estimated uptake	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.	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&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. Report: Human resource and skill requirement in Health sector is available at https://www.ugc.ac.in/skill/SectorReport/Healthcare.pdf

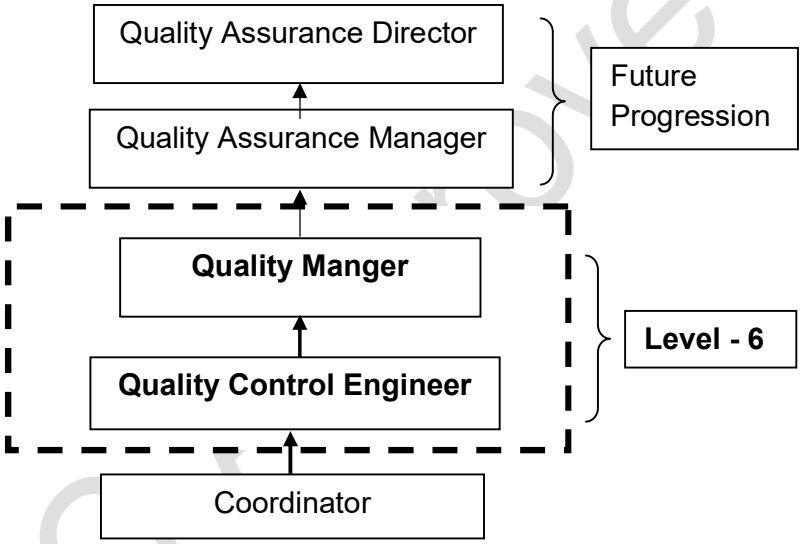
27	**Recommendation from the concerned Line Ministry of the Government / Regulatory Body. To be supported by documentary evidences** Department of Health & Family Welfare
28	**What steps were taken to ensure that the qualification(s) does (do) not duplicate already existing or planned qualifications in the NSQF? Give justification for presenting a duplicate qualification** 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. 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 & strategic committee. These committees are comprising of senior biomedical engineers, industrial experts and experienced academicians.
29	**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** i. IBSC office monitors the screened candidates periodically as per the module. ii. The review report generated on the basis of previous response by the candidates & benefits candidate on the professional front. iii. The technical committee will be informed to revise the syllabus & question bank for continuous improvements. iv. Qualification is reviewed after every three years for updating according to latest technologies & practices.

SECTION 4
EVIDENCE OF PROGRESSION

30	**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?** ***Show the career map here to reflect the clear progression***

The Certification program designed for "Certificate in Biomedical Quality Assurance" in each level, 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).

Certificate in Biomedical Quality Assurance – Career Graph



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