National curriculum and assessment guidelines in preparation for registration as a Medical Biological Scientist
1. **Disciplines**

- Haematology
- Microbiology
- Virology
- Immunology
- Anatomical Pathology
- Clinical Anatomy
- Human Genetics
- Molecular Biology
- Reproductive Biology
- Cell Biology
- Pharmacology
- Physiology
- Radiation Biology
- Clinical Biochemistry

2. **Criteria for accepting interns for training**

   The intern must be in possession of a 4-year science degree (equivalent to a BSc Honors degree)

3. **Duration of training & supervision**

3.1 24 months for candidates with a BSc (Hons) degree

3.2 Candidates with a **relevant** MSc or PhD, i.e. the area of research must be aligned with the appropriate discipline, may apply to the HPCSA for a shortened internship – 6-18 months for an intern who has an MSc or PhD. A shortened internship is at the discretion of the supervisor, must be approved by the HPCSA and is decided on a case by case basis. Such candidates are not required to carry out a research project during their internship however competencies for all other elements of the training program must be achieved. At the time of intern registration, a letter of motivation from the supervisor requesting a shortened internship should be submitted for consideration by the committee. If no such letter is submitted it will be assumed that the candidate will complete a 2-year internship.

3.3 Supervision of training must be undertaken by either a pathologist or scientist with a minimum of 3 years registration with the HPCSA.
3.4 Supervisors and interns are not to confuse scientist intern training with postgraduate training (MSc or PhD). The primary goal of an internship is to build skill and competency in a diagnostic environment, which is not the purpose of a research Masters or PhD. Interns are therefore not encouraged to simultaneously undertake a postgraduate degree (e.g. MSc or PhD).

3.5 HPCSA-accredited training institutions are required to develop their own detailed scientist intern training programs incorporating all of the elements mentioned below. Training programs need to be submitted to the HPCSA for approval at the time of applying for accreditation (for scientist intern training). Interns will be assessed based on the submitted program.

4. Overall outcomes

At the end of formal training, a medical biological scientist should have gained knowledge, expertise, skill and a certain degree of experience in the following areas:

4.1 The application of basic scientific principles

4.2 Performance of laboratory methods in accordance with standard operating procedures and interpretation of results relevant to a laboratory diagnostic environment. This needs to be done in an accredited diagnostic environment and not in a research environment.

4.3 Administration and management of a laboratory and the service in general and be able to demonstrate an understanding of the process within an accredited diagnostic environment.

4.4 Application of ethical principles, good clinical practice and good laboratory practice in the practice of clinical diagnostics.

4.5 Database/s used in a diagnostic laboratory environment
5. **Specific outcomes**

5.1 **Medico-legal and ethics**

At the end of formal training, a medical biological scientist must have knowledge and understanding (where relevant for the appropriate discipline) of:

5.1.1 HPCSA guidelines which cover concepts such as responsibility, accountability, consent, confidentiality and disclosure in terms of professional conduct and patient care including reasonable practice and practicing in good faith

5.1.2 The relevant Acts such as the Occupational Health and Safety Act, Compensation for Occupational Injuries and Diseases Act, National Health Act including the regulations of the HPCSA, Labour Relations Act especially the aspects regarding HIV/AIDS and the Human Tissue Act

5.1.3 Ethics of dealing with patients and patient samples

5.1.4 Ethics applicable to research

5.2 **Good laboratory practice (GLP) and laboratory safety**

At the end of formal training, a medical biological scientist must have knowledge and understanding of:

Laboratory safety and GLP including:

5.2.1 Correct use of personal protective equipment (laboratory coats, gloves, masks, goggles, as appropriate)

5.2.2 Handling, storage and disposal of biological specimens

5.2.3 Handling, storage and disposal of chemicals (including radioactive materials where applicable)

5.2.4 Managing chemical and biological spills (including radioactive materials where applicable)

5.2.5 Fire hazards and safety drills

5.2.6 Where applicable, safe transport of specimens including the process of importing and exporting biological materials/tissue to and from South Africa in accordance with the Department of Health regulations
5.2.7 Physical and ergonomic hazards and safe handling of equipment

5.3 Laboratory methods

At the end of formal training, a medical biological scientist must have knowledge and understanding of:

5.3.1 Organization of work, time management and the use of laboratory protocols and SOP’s

5.3.2 How to operate and maintain basic laboratory equipment

5.3.3 How to operate and maintain specialized laboratory equipment pertaining to the specific discipline

5.3.4 Validation of assays and instruments including concepts of specificity, sensitivity, accuracy, precision, linearity, detection limits, replication, reference intervals and predictive value

5.3.5 Compilation of diagnostic reports according to established quality standards.

5.4 Laboratory accreditation

At the end of formal training, the medical biological scientist should have knowledge and understanding of:

5.4.1 Quality management

5.4.2 Quality assurance

5.4.3 Laboratory accreditation

5.4.4 Quality controls

5.4.5 Internal and external quality assessment programs

5.5 Research methodology

At the end of formal training, a medical biological scientist must have knowledge and understanding of:

5.5.1 Academic discourse (can be achieved through journal club discussions/presentations)

5.5.2 Critical review of the literature
5.5.3 Defining a research question/hypothesis and developing the proposal/protocol

5.5.4 Ethics application for a research protocol (through the relevant university and/or provincial ethics committee)

5.5.5 Study design

5.5.6 Executing the research

5.5.7 Data management, analysis and interpretation, critical thinking

5.5.8 Presenting research findings through writing up a research report and/or presentation at research meetings/academic days/conferences/departmental seminars

5.5.9 Basic biostatistics where applicable

5.5.10 Application of ethical principles, good clinical practice and good laboratory practice in the practice of research and within an accredited diagnostic testing environment

5.5.11 Referencing techniques/methods and citation

5.5.12 Funding processes and budgeting

5.6 Discipline-specific requirements

To be detailed in individual institutional or departmental training programs. The program should encompass specific details of relevant laboratory assays and processes for that discipline, academic program (journal clubs, seminars, tutorials, presentations etc.), and in-house assessments (tests, assignments, tasks, case studies etc).

At the end of formal training, the medical biological scientist should have knowledge and understanding of the core elements for that discipline.

6. Training assessment

A formal assessment process will be conducted to ensure the candidate has acquired the necessary skill/knowledge outlined in the syllabus.

The assessment is in the form of a submitted portfolio which needs to include the following elements:

6.1 A cover page with the intern’s name, discipline, affiliation, contact details and date
6.2 A contents page including page numbers

6.3 A copy of the HPCSA certificate of registration as an intern

6.4 A cover letter from the person responsible for the intern training program stating the following:

6.4.1 Start and end dates and approved duration of internship. This is important as these may deviate slightly from the HPCSA certificate due to the delay in registration or processing the registration application.

6.4.2 Elements of the training program that the candidate had already completed prior to commencing the intern scientist training program (especially for candidates completing a shortened internship)

6.4.3 A description of the intern's responsibilities prior to and during the internship.

6.4.4 Any other relevant information on the candidate.

6.5 A copy of the intern training program as accredited by the HPCSA that includes a list of all staff (scientists, medical technologists, pathologists) involved in the training.

6.6 *Curriculum vitae* of the candidate

6.7 A summary of the candidate’s training according to the approved training program signed by the candidate and verified by the internal assessor/supervisor. The emphasis here is on a summary of competencies achieved that are documented in the logbook including all generic and discipline specific elements of the training. Evidence of work completed should be included for all major sections of the training.

6.8 A list of academic topics covered in journal clubs and/or tutorials indicating the date and by whom these were presented including where the candidate was the presenter. It is useful to indicate the sources of the information presented (text books and/or journal articles)

6.9 A list of other academic contributions by the candidate such as seminars, conference presentations, case studies etc.

6.10 A research report which includes Introduction, Methods, Results, Discussion and References. The research project for internship can be a R&D project evaluated internally. In the case where a dissertation/thesis has already undergone external evaluation and been approved (e.g. for an MSc or PhD degree), a letter to this effect can be included.
6.11 Documentation on all forms of assessment done during the training needs to be included. It is important to note that proof of skills/competency should be in the form of tests/assignments/case studies or similar. Proof of training alone is insufficient.

6.12 A final exit assessment of competency in the form of a signed letter by the head of the training program or supervisor has to be included.

7. **Portfolio evaluation and moderation**

7.1 Portfolios may be submitted twice annually for examination – the submission deadlines are 31 March or 30 September annually. Portfolios may be submitted at any stage during the year but will only be assessed during one of these two periods i.e. May/June (for March submissions) or Oct/Nov (for Sept submissions).

7.2 Portfolios are assessed by 2 independent assessors followed by moderation by a third party.

7.3 The process takes approximately 8 weeks following which the HPCSA will inform the supervisor and intern of the outcome.

7.4 In order to facilitate and speed up the assessment process, supervisors and/or interns are advised to communicate their intent to submit a portfolio to the HPCSA at least one month before submission.

7.5 Where portfolios are not approved i.e. inadequate/insufficient training, the supervisor and intern will be notified in writing. Interns will be required to submit the requested documentation or complete the missing elements of their training before registration can be approved.

7.6 Interns are advised to complete the full period of internship before submitting their portfolio. Earlier submission (1-3 months before the March or September deadlines) by interns not wanting to miss the date deadline may be permitted provided the training program has been completed, or will be completed within 1-3 months after submission (proof of completion of outstanding training must be submitted before registration can be approved). However, as per HPCSA regulations, final registration by the Registration Department can take place only once the 6-, 12-, 18-, or 24-month period of internship has passed.

7.8 If required, an internship period may be extended (for valid reasons). Please communicate the intention/request to the HPCSA, clearly stating the reasons why the internship should be extended.
8. **Required forms**

(Forms can be downloaded from [http://www.hpcsa.co.za/Registrations/ApplicationForms](http://www.hpcsa.co.za/Registrations/ApplicationForms))

8.1 When registering as a MEDICAL BIOLOGICAL SCIENTIST INTERN please complete and submit **FORM 26 MSIN**. Interns need to submit within 2 months of commencing intern training

8.2 **FORM 36 MS** to be submitted together with portfolio submission

8.3 Following completion of training, please complete and submit **FORM 24 MS** to register as a MEDICAL BIOLOGICAL SCIENTIST. This may be submitted at the same time as portfolio submission in order to speed up the process (provided portfolio assessment is successful)