Quality Management System {ISO 13485:2016) Certification Audit Specifications for all NHLS Diagnostic Media Products: Greenpoint, Sandringham, Port Elizabeth and KZN

- Audit Man-days to be determined by the SAPRAH approved service provider.
- Follow the ISO 13485:2016 Standard requirements for certification of the NHLS DMP laboratories.
- The assessments will be conducted at planned intervals as per each department plan or request.
- The cost for the audit should be broken down per department as the audits will not be requested or conducted at the same time.
- Invoicing of the service to be provided should be broken down by audit stages of the certification process.
- To assess the Quality Management System (QMS) for NHLS Diagnostic Media Products X4 for the requirements of ISO 13485:2016 for the following activities, outlined in table 1-table 4 below.
- The contract for the panel of service providers is proposed to be for 5 years.

Table 1. Green Point Diagnostic Media Products (DMP) Processes

Process	Processes
Management	Quality Policy Knowledge Customer requirements Historical performance Organogram
Resources	Volume and Revenue Organograms Capex/Procurement process MRM output Policy and Procedure list Equipment asset list Equipment maintenance schedule Monthly report

Process	Processes
DMP Operations 1. Planning of production 2. Production 3. Internal quality control and release of product 4. Finished goods dispatch	Customer order On hand stock availability Daily production planning and volumes QC daily production template information Released product
Measurement and analysis: Performance evaluation	Data for quality objectives Customer survey and feedback Internal audit schedule MRM inputs
Improvement	Data trends Nonconformity Customer feedback and survey Opportunities Qualitv obiectives

Table 2. Port Elizabeth Diagnostic Media Products (DMP) Processes

Process	Input
Management	Internal Audits Non-conformances and corrective actions Document/Record control procedures Management review Quality Policy Quality Objectives Customer satisfaction
Outsourced Processes	Procurement of raw materials Information Technology Transport and delivery

Process	Input
DMP Operations 1. Production ✓ Planning ✓ Production procedure ✓ Planning and development of new products 2. Production 3. Internal quality control and release of product 4. Finished goods dispatch	Customer order Daily production planning and volumes QC daily production template information Released product
Sales Internal and external sales	Data for quality objectives Customer survey and feedback On hand stock availability
Improvement	Data trends Nonconformity

Table 3. Diagnostic Media Products (DMP) Sandringham

Process	Processes
Management	Internal Audits Non-conformances and corrective actions Document/Record control procedures Management review Quality Policy Quality Objectives Customer satisfaction
Production	Confirmation of raw material Product scheduling

Process	Processes
	Printing of batch sheets Production of media and reagents
Quality Assurance	Collection of products and batch sheets Quality control External quality control Appearance check Performance check Sterility check Release of products
Stores and Distribution	Capturing of released product Printing of picking notes Picking and packing Stock take Purchasing Dispatch Shipping

Table 4. Diagnostic Media Products (DMP) KZN

Pro{;ess	Processes
Management	Non-conformances and corrective actions Document/Record control procedures Customer satisfaction
Production	Confirmation of raw material Printing of batch sheets Production of media and reagents
Quality Assurance	Collection of products and batch sheets Quality control Appearance check Performance check Sterility check Release of products
Stores and Distribution	Picking and packing Stock take Purchasing. Dispatch Shiooino

SECTION2: Staff Complement for each unit

- Staff complement for each department is outlined below
- This total number includes services which operates at regional offices

Unit	Corporate	Regions
DMP - Green Point	0	17
DMP- Port Elizabeth	0	14
DMP- Sandringham	28	0
DMP- Kwa Zulu Natal	0	14

NATIONAL TENDER FOR A PANEL OF SERVICE PROVIDERS FOR CERTIFICATION OF NHLS DMP FACILITIES

REVISED FUNCTIONALITY SPECIFICATIONS - ISO 13485:2016

Purpose: To appoint suitably accredited and competent certification bodies to provide ISO 13485:2016 certification services for NHLS Diagnostic Media Products (DMP) fac1ht1es. The evaluation is structured to distinguish mandatory compliance requirements from scored technica functionality requirements

A. Technical Mandatory/ Pre-Qualification Requirements

The following requirements should be evaluated as mandatory compliance requirements and should not form part of the functionality score. Failure to meet a mandatory requirement should render the bid technically non-responsive, subject to the applicable NHLS Supply Chain Management rules.

No.	Mandatory requirement	Soeclfication	Required evidence
1	Accreditation of the certification body	The bidder must be an accredited management system certification body with a valid scope of accreditation covering ISO 13485:2016 certification, issued by SANAS or another accreditation body that is a signato,y to the applicable IAF Multilateral Recognition ArranQement **(MLA)**.	Valid accreditation certificate and current scope of accreditation explicitly covering ISO 13485:2016.

B. Functionality Evaluation

Only bidders that satisfy all mandatory requirements should proceed to functionality evaluation. The recommended min'mum functionality threshold is 80 out of 100 points.

No.	Functionality criterion	Weight	Specifications	Required evidence	Scoring guideline
1	Demonstrated ISO 13485 certification experience	25%	Demonstrable experience providing ISO 13485 certification services. Preference should be given to bidders with at least five years' relevant certification exoerience.	Company profile and verifiable reference letters/contracts confirming ISO 13485 certification work.	:.:5 years with :.:5 relevant certification clients= 25; ;.:5 years with 3-4 clients = 20; 3-<5 years with ;.:3 clients = 15; <3 years or limited evidence = 5; no relevant evidence = 0.
2	IVD / medical device manufacturer certification experience	20%	Demonstrated experience certifying in-vitro diagnostic (IV☐)and/or medical device manufacturers of comparable size, complexity and reQulatorv environment.	Reference letters or certification project records identifying IVD/medical device clients and scope.	;.:5 comparable IVD/medical device clients = 20; 3-4 = 15, 1-2 = 8; none= 0
3	Qualifications and competence of proposed ISO 13485 auditors	20%	Auditors proposed for the NHLS engagement must hold recognised medical device QMS auditor/lead auditor qualifications (e.g., IRCA or equivalent) and demonstrate competence to audit ISO 13485:2016.	CVs, auditor/lead auditor certificates, training records and evidence of relevant audit experience	100% of proposed auditors appropriately qualified and :.:5 years relevant experience = 20; all qualified with 3-<5 years= 15; partial team compliance = 8 insufficient evidence = 0.
4	IV☐/ medical device technical competence of the audit team	15%	The proposed audit team must demonstrate sector-specific competence relevant to medical devices and, preferably, IVD	CVs, sector codes/competence records, training records and list of relevant audits performed.	Strong IVD-specific competence across the team = 15; medical-device competence with some IV☐ exoosure = 1O qeneral

No.	Functionality criterion	Weight	Specification	Required evidence	Scoring guideline
			manufacturing, including understanding of applicable QMS and regulatory interfaces.		medical-device exposure only = 5; no demonstrated sector competence = 0.
5	Proposed certification methodology and implementation plan	10%	The bidder must provide a clear methodology covering certification planning and the applicable certification cycle, including Stage 1, Stage 2, surveillance and recertification activities; management of nonconformities; reporting; certification decision-making; and communication with NHLS.	Technical proposal, methodology, implementation plan and indicative deliverables/timelines.	Comprehensive, clear and fully responsive methodology = 10; adequate methodology with minor gaps = 7; partially responsive = 4; inadequate/no methodology= 0.
6	Capacity and resources to service NHLS DMP facilities	5%	Demonstrated capacity to provide certification services across the required NHLS DMP facilities within agreed timelines, including availability of suitably competent auditors.	Resource plan, auditor availability, geographic coverage and proposed scheduling approach.	Fully demonstrated capacity = 5; adequate but with limitations = 3; insufficient capacity= O.
7	Performance on comparable certification contracts	5%	Demonstrated satisfactory performance on comparable ISO 13485 certification contracts.	At least three contactable client references, preferably from medical device/IVD organisations.	3 or more satisfactory references = 5; 2 = 3; 1 = 1; none= 0.

TOTAL FUNCTIONALITY SCORE: 100%

MINIMUM FUNCTIONALITY THRESHOLD: 80%

C. Additional Technical Conditions

- The certification body must maintain its applicable ISO 13485 accreditation for the full duration of the contract.
- Auditors allocated to NHLS must be demonstrably competent for the assigned medical device/IVD scope and must be independent and impartial.
- The bidder should identify the proposed audit team and may not substitute key auditors without prior notification and evidence of equivalent competence.
- The certification approach must address the applicable certification cycle, including initial certification activities, surveillance and recertification.
- Audit reports must clearly document findings, nonconformities and the basis for certification decisions.
- Certification decisions must be made through the certification body's established independent certification decision process
- The bidder must maintain confidentiality of NHLS information obtained during certification activities.
- Where multiple DMP facilities are included, the bidder must describe its approach to planning and coordinating audits across the relevant sites.

D. Evaluation Principle

Administrative compliance and accreditation requirements should be assessed before functionality Functionality scoring should evaluate only the bidder's technical competence, relevant ISO 13485/IVD experience, methodology, resources and demonstrated ability to deliver the required certification services. The evaluation committee should apply the approved scoring criteria consistently and retain supporting evaluation records for each score awarded

E. Definitions

- IVD- Medical test and devices used to analyze human biological samples
- Medical device- Any tool, machine, software, implant or material used to prevent diagnose, monitor or treat disease, injury or disability