ACCREDITATION CHALLENGES IN PHARMACEUTICAL LABORATORIES

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ACCREDITATION CHALLENGES IN PHARMACEUTICAL LABORATORIES

- Introduction
- Financial Challenges
- Management commitment
- Infrastructural Challenges
- Technical Personnel Competencies & Retention

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STRUCTURE OF THE PRESENTATION (ctd)

- Laboratory Equipment
- Calibration Service Providers
- Supplies of critical consumables and reference standards
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- Sub-contracting of testing work
- Proficiency Testing Schemes
- ISO Accreditation versus WHO Pre-Qualification
- Conclusion

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INTRODUCTION

What is Laboratory Accreditation?
Why laboratory Accreditation?
What are the benefits?

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INTRODUCTION

- It is always a challenge for most laboratories to obtain and maintain ISO 17025 Accreditation (Long process/ expensive project with long term benefits) e.g. increased business; credibility of results; etc)

- In Zimbabwe only MCAZ has the accredited Pharmaceutical Laboratories (Chemistry & Medical devices)

- The facility got Accredited despite the difficult challenges
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INTRODUCTION

- Most similar Pharmaceutical laboratories are battling with the choice of having to go for either WHO Pre-Qualification or ISO 17025 Accreditation.

- Accreditation challenges for the Pharmaceutical Laboratories in Zimbabwe are centred on the high project costs, limitations on infrastructure, technical personnel competencies and staff retention, equipment, suppliers of calibration service and critical consumables and availability of relevant PT schemes.
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FINANCIAL CHALLENGES

- Initial / set-up costs of a Quality Management System
- Accreditation costs (system Development & Implementation, document reviews, assessments and maintenance of the laboratory accreditation)
- Benefits of ISO 17025 Laboratory Accreditation to the National Regulatory Testing laboratory
- Benefits of ISO 17025 accreditation to the Pharmaceutical manufacturing laboratory (confidence building and laboratory recognition) since WHO Pre-qualification is rather too involved and involves all aspects of the laboratory

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MANAGEMENT COMMITMENT CHALLENGES

- Senior management failure to appreciate the benefits of laboratory accreditation (why? / how much?)

- Some organisations focus on either ISO 9001 certification, WHO Pre-Qualification before considering ISO Laboratory accreditation (implications of each system?)
Some laboratory designs fail to meet the minimum requirements for the ISO 17025 accreditation and that tends to discourage management to spend money on renovations.
TECHNICAL PERSONNEL & STAFF RETENTION

- Laboratory personnel are qualified based on the relevant qualifications, experience and competencies.

- The major challenge is on recruitment, training and competence assessment of the personnel.
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TECHNICAL PERSONNEL & STAFF RETENTION

- All technical personnel must be assessed and be deemed competent as Technical Signatories by an independent assessor/Assessors from the Accreditation body before they can be allowed to test and generate test reports under the scope of Accreditation.

- Once personnel are deemed competent, they become more marketable and are motivated to move-on if retention strategies are not in place thus affecting the accreditation status.
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LABORATORY EQUIPMENT

- The laboratories must always have the right equipment that is consistent with the current technological advances.

- The equipment must meet the current minimum technical requirements for it to be used for the scope of accreditation.

- All equipment must be serviced and maintained as per approved program.

- Back up spares for the high-tech equipment must be guaranteed to ensure continued accreditation. Example of the equipment is; HPLC, UV-Vis Spectrophotometer, etc)

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CALIBRATION SERVICE PROVIDERS

- There are no adequate accredited service providers for the calibration services. (only one service provider is accredited but does not cater for the critical laboratory equipment in the Pharmaceutical laboratories)

- At times the accredited scope of the service provider does not match the scope of the accredited facility and hence some challenges will arise.

- The high service fees being charged by the monopolistic suppliers are very prohibitive to industry and discourage potential accreditation initiative.

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SUPPLIERS OF CRITICAL CONSUMABLES

- There are no accredited suppliers of critical reagents, consumables and reference standards for both Chemistry and Microbiology laboratory tests.

- This has resulted in high consumable costs (reagents and media) that discourages the approval of the accreditation initiative.
Some of the Pharmaceutical companies rely on sub-contracting some of their testing activities.

Once a facility is accredited, it can only sub-contract to another accredited testing facility to ensure traceability of the quality control testing processes.
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PROFICIENCY TESTING SCHEMES

- Proficiency Testing Schemes and inter-lab comparisons are key to any accreditation process.

- The relevant PT schemes for the Pharmaceutical testing techniques are not available in Zimbabwe and the SADC/COMESA region.

- Currently, the accredited laboratories depend on annual international Proficiency Testing Schemes and intra-laboratory comparisons in order to maintain the minimum requirements for accreditation.

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ISO 17025 ACCREDITATION VERSUS WHO PRE-QUALIFICATION

- The ISO accreditation process allows for a narrow scope as a measure to assure adherence to quality management systems while WHO Pre-Qualification focuses on all activities within a laboratory.

- In an ISO accredited facility, test reports are only authorised by assessed and competent technical signatories while in the WHO PQ laboratory, it can be authorised by competent personnel not necessarily a technical signatory.

- ISO accreditation process allows for a step by step approach where the scope of accreditation will be widened with time while pre-qualification focuses on all activities within the laboratory.
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CONCLUSION

- In conclusion, a lot is still to be done by way of articulating the challenges that have until now, discouraged the Pharmaceutical Laboratories from embracing the benefits of ISO 17025 Laboratory accreditation.

- Awareness should be done on the benefits of being ISO 17025 accredited against the start-up costs and other challenges given that the concept of “tested once, accepted everywhere”.

- A lot has to be done by the accreditation bodies and relevant laboratory associations to ensure an improved level of awareness in the pharmaceutical sector.
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CONCLUSION

➢ The laboratory associations must spearhead the formation of relevant PT Schemes for the pharmaceutical testing laboratories.

➢ The laboratory associations must ensure that more calibration service providers become accredited or at least that they start working towards implementing the ISO 17025 QMS.

➢ The sector must also start to invest into technologically compliant laboratory equipment and put in place relevant retention strategies for technical staff.

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Thank you for your attention!!

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