INTRODUCTION

In an effort to build African capacity for providing PT services in the pharmaceutical sector, the EAC Secretariat in cooperation with PTB (the German Metrology Institute) started to support Pharma R&D lab to become a regional PT provider for testing laboratories.

PT is a valuable tool for Pharma testing laboratories to demonstrate testing competencies as a requirement for ISO/IEC 17025 accreditation.

Participants in this scheme include NQCL of the NMRAs, pharmaceutical manufacturing QC labs, National bureau of Standards (NBS), universities and others within the EAC, neighboring countries and later rolled over the entire continent.

METHODOLOGY

Planning and execution: ISO/IEC 17043:2010 Conformity requirement

Statistical evaluation as per requirement ISO 13528

- Determination of assigned value: consensus value from participants with target RSD set at 2.5 %
- Z-score – biased estimate of the results (mean value, assigned value and target RSD) + kernel density
- Cochran’s test - checking for higher RSD
- Grubbs’ test – checking for outlying means

STEPS INVOLVED

1. Preparation of PT material and protocol
   - PT provider: homogeneity testing
2. Distribution of PT material and protocol to participants
   - PT provider: stability testing
   - Participants: sample analysis
3. Data analysis
   - Participants: send raw data
   - PT provider: statistical analysis
4. Preliminary PT report
5. Evaluation workshop: PT provider and participants
6. FINAL PT report

RESULTS

Table 1: REGIONAL DISTRIBUTION OF PARTICIPANTS

<table>
<thead>
<tr>
<th>R/N</th>
<th>TANZANIA</th>
<th>KENYA</th>
<th>UGANDA</th>
<th>DJIBOUTI</th>
<th>RWANDA</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>6</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>Congo DRC, Ethiopia, Ethiopia</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1 (Ethiopia)</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td></td>
<td>3 (2 Ethiopia and 1 Seychelles)</td>
</tr>
<tr>
<td>9</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td></td>
<td>3 (1 Ethiopia, 1 Seychelles and 1 Germany)</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td></td>
<td>Congo DRC, 1 Seychelles, Nigeria, 1 Burundi, 1 Zimbabwe, 1 Mali</td>
</tr>
</tbody>
</table>

CONCLUSION

Six locally organized African PT schemes within Pharma testing Labs
A great opportunity for both the provider and participants to follow the lessons learned, which forms the ground for Continuous Quality improvements.

The experience gained is helpful for further maintenance of the ISO/IEC 17043 accreditation status

Appeals to African Pharma testing labs to actively participate and demonstrate competence

ACKNOWLEDGEMENTS
MUHAS, PTB, EAC SECRETARIET, ALL PARTICIPANTS