Plant Aeroview
Fermentation Facility
Extraction Facility
Clean Room Operation

Clean room
Registration in U.S. FDA

➢ Kanamycin Monosulfate                  DMF no.: 28275
➢ Vancomycin HCL, Lyophilized       DMF no.: 26030
➢ Vancomycin HCL, Precipitated        DMF no.: 26310
➢ Colistimethate sodium                      DMF no.: 28350
➢ Daptomycin                                          DMF no.: 29137
EDQM

➢ Colistin Sulfate
   CEP No : R0-CEP 2011-372-Rev 00

➢ Vancomycin HCL, Precipitated
   CEP No.: R0-CEP 2012-235-Rev 00

➢ Teicoplanin
   CEP No. : R0-CEP 2015-093-Rev 00
Confirmation of WHO API Prequalification (CPQ)

- **Kanamycin Monosulfate**
- **Ref. No.: APIMF-246**
- **Kanamycin Acid Sulfate**
- **Ref. No.: APIMF-241**
WHO PQ Experiences 1

2011  WHO PQ made numerous requested to have a site GMP Inspection on sterile Kanamycin Acid Sulfate.
At the time, Livzon Fuzhou Fuxing did not submitted APIMF to WHO PQ.

In order to accommodate WHO PQ’s need to address kanamycin sulfate FPP shortage, the first WHO PQ site inspection is hosted at the end of 2011.

Dr. Andre Van Zyl I led the GMP inspection resulted some critical observations
(non data-integrity related)

At the exit meeting, there was no conclusion that the GMP inspection was not in compliances with WHO PQ GMP guidelines.
2012  USP GPH PQM directly involved to provide technical assistance on how to complete CAPA plan with some completed CAPAs.

However, in April 2012, WHO PQ issued a closing letter to announce Fuzhou Fuxing Sterile Kanamycin Acid Sulfate was no in compliance with WHO PQ GMP.

It was interrelated that this process was hopeless to pass WHO PQ inspite numerous USFDA and EDQM approvals for the other APIs on the site.

April 22, 2012  PQM made a site visit to emphasis the importance of WHO PQ to the management while remote technical assistance were ongoing.

May 12, 2012  PQM provided an audit on the CAPA results.

June 6, 2012  A site technical assistance on CAPA was conducted as necessary.

Aug 8, 2012  PQM was on site to make sure all the CAPAs were completed for WHO PQ reviews.
WHO PQ Experiences 3

Jan 2014  USP GPH PQM brought WHO PQ Sterile expert David Buckley for a mock audit (who became a third party GMP consultant for WHO PQ, also for manufacturers)

Jan-Feb 2014 PQM provided technical assistance to the CAPA based on the mock audit.

Feb 14, 2014 WHO PQ 2nd inspection
Some observation required bench mark GMP to complete the CAPA

Sept 2014 PQM provided a site visit for the CAPA follow up.

May 2015 PQM conducted another mock audit for the WHO PQ inspection.

July 2015 WHO PQ inspection resulted a WHO PQ GMP compliance.

Feb 2016 WHO Prequalification achieved.

Besides the site visits, USP GPH PQM provided invaluable remote technical assistances To GMP issues and dossier questions from WHO PQ dossier assessment team.
Conclusions

• Technical Assistance are hands-on and technically intensive.
• Overcoming Communication and cultural barriers is as important as technical matters.
• Requiring mental strengthen to deal with world renowned inspectors.
• Without USP GPH PQM’s Technical Assistance, a WHO PQ process could be much longer.
Acknowledgement

The technical assistance from USAID aided USP GPH PQM towards kanamycin acid sulfate API for WHO PQ is great appreciated to enable Livzon Fuzhou Fuxing Pharma to make a contribution to the global public health.
Thank You