PLASMA PRODUCT LOT RELEASE : COLD CHAIN INSPECTION

1 ST DIALOGUE SESSION

DEWAN ANGGERIK BPFK

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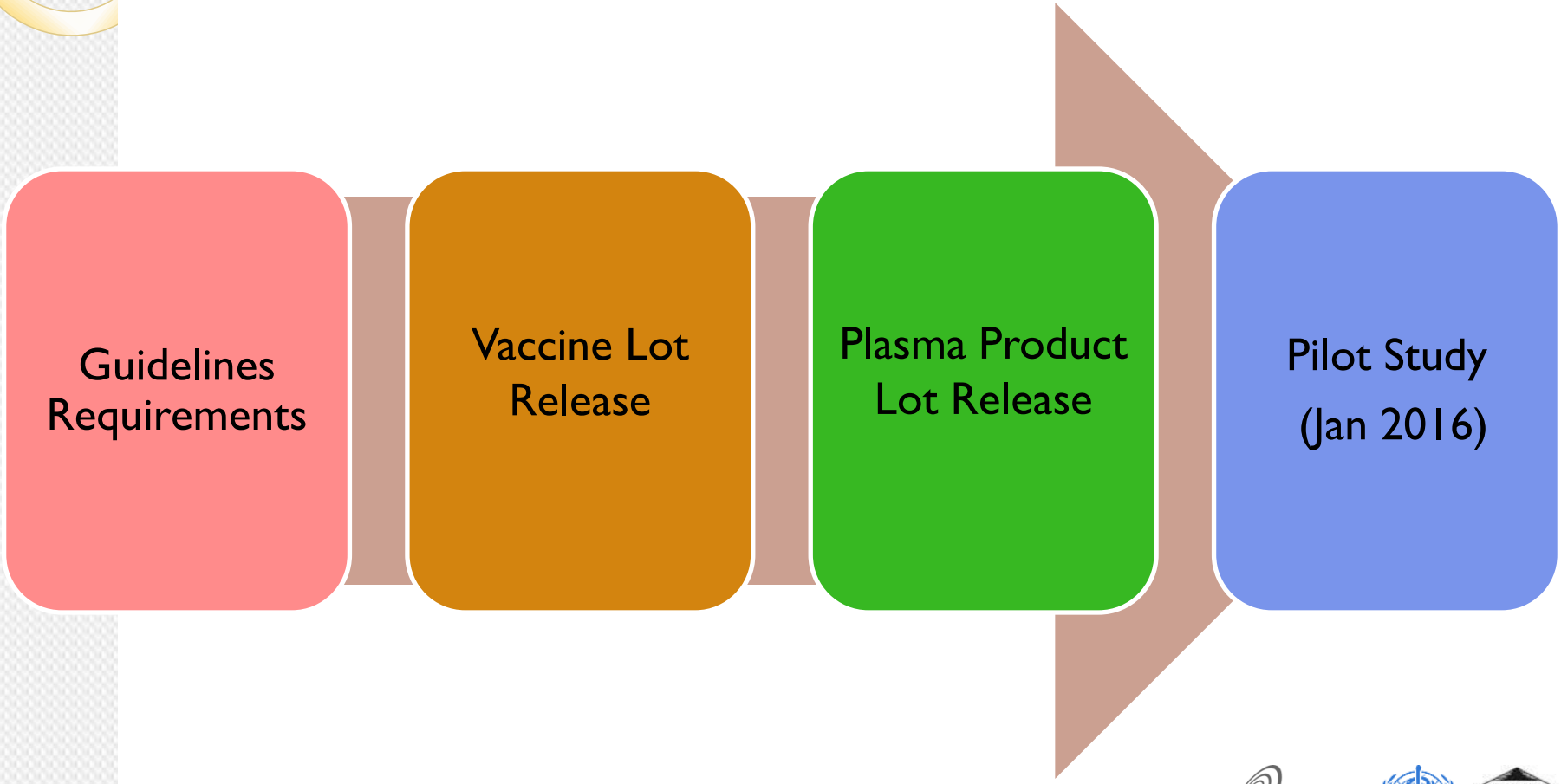
Introduction

- Plasma Product Lot Release = Documentation Review (Lot Summary Protocol/LSP) + Assessment of Cold Chain System Monitoring (Cold Chain Inspection/ CCI)
- Pilot Study to commence Jan 2016
- Full Implementation – July 2016

List of Product Registration Holder (PRH) and Importer

No	PRH/ Importer
1	Baxter Healthcare (M) Sdn Bhd
2	Germax Sdn Bhd
3	Grifols Malaysia Sdn Bhd
4	Pharmaniaga Marketing Sdn Bhd
5	Propharm (M) Sdn Bhd
6	Pusat Darah Negara
7	United Italian Trading (M) Sdn Bhd
8	Pahang Pharmacy Sdn Bhd
9	Pharmaforte (M) Sdn Bhd

Cold Chain Inspection



Guidelines on Good Distribution Practice (GDP), 2nd Edition 2013

- Compliance towards Good Distribution Practice (GDP) Guideline requirements
- Enforced since 1st January 2012
- For all local manufacturers/ importers/ wholesalers of registered products/ notified cosmetic
- Inclusive of Chapter 15 (Management of Cold Chain Products/ Materials) – Guidelines on GDP Second Edition 2013

Chapter 15 : Management of Cold Chain Products/ Materials

- Main points included:

- Qualification & validation of storage facility (15.3)
- SOPs for receiving & storage (15.5), distribution(15.4), packing(15.15 & 15.16), out-of-specification (15.23)
- Temperature mapping, monitoring, record (15.8-15.10)
- Maintenance of equipment (air conditioning system, refrigerator) (15.11) and calibration (temperature monitoring devices) (15.14)
- Alarm system (15.12)
- Alternative power system/ area (15.13)
- Transportation (15.19-15.22)

Other References

- Annex 9 - **Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products**, WHO Technical Report Series, No. 961, 2011
- PIC/S Guide to Good Distribution Practice for Medicinal Products , PE 011-1, June 2014

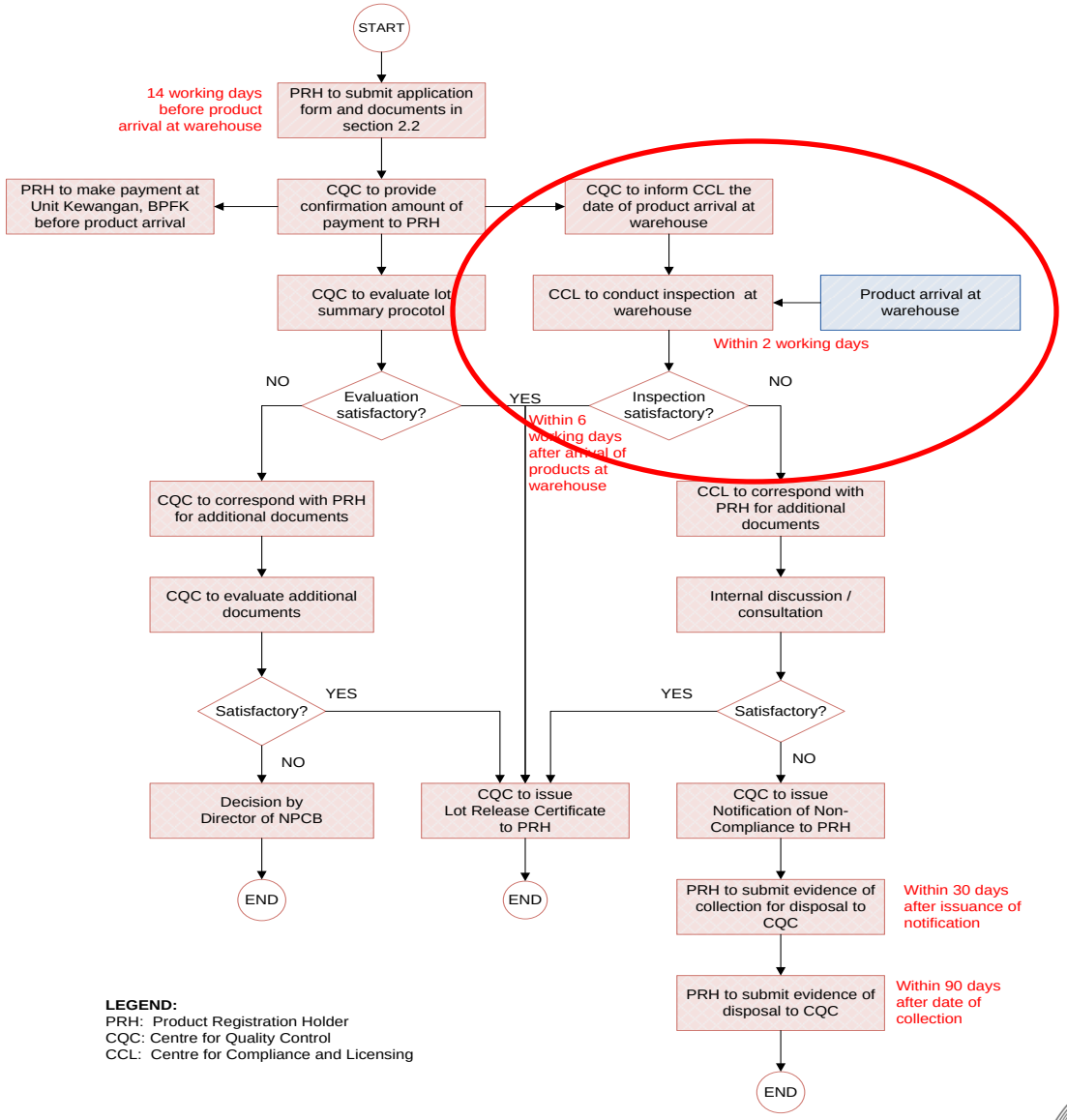
Cold Chain Inspection - Process

Receive Application

Inspection on Site *

Approve/Reject

Centre for Compliance and Licensing
NATIONAL PHARMACEUTICAL CONTROL BUREAU

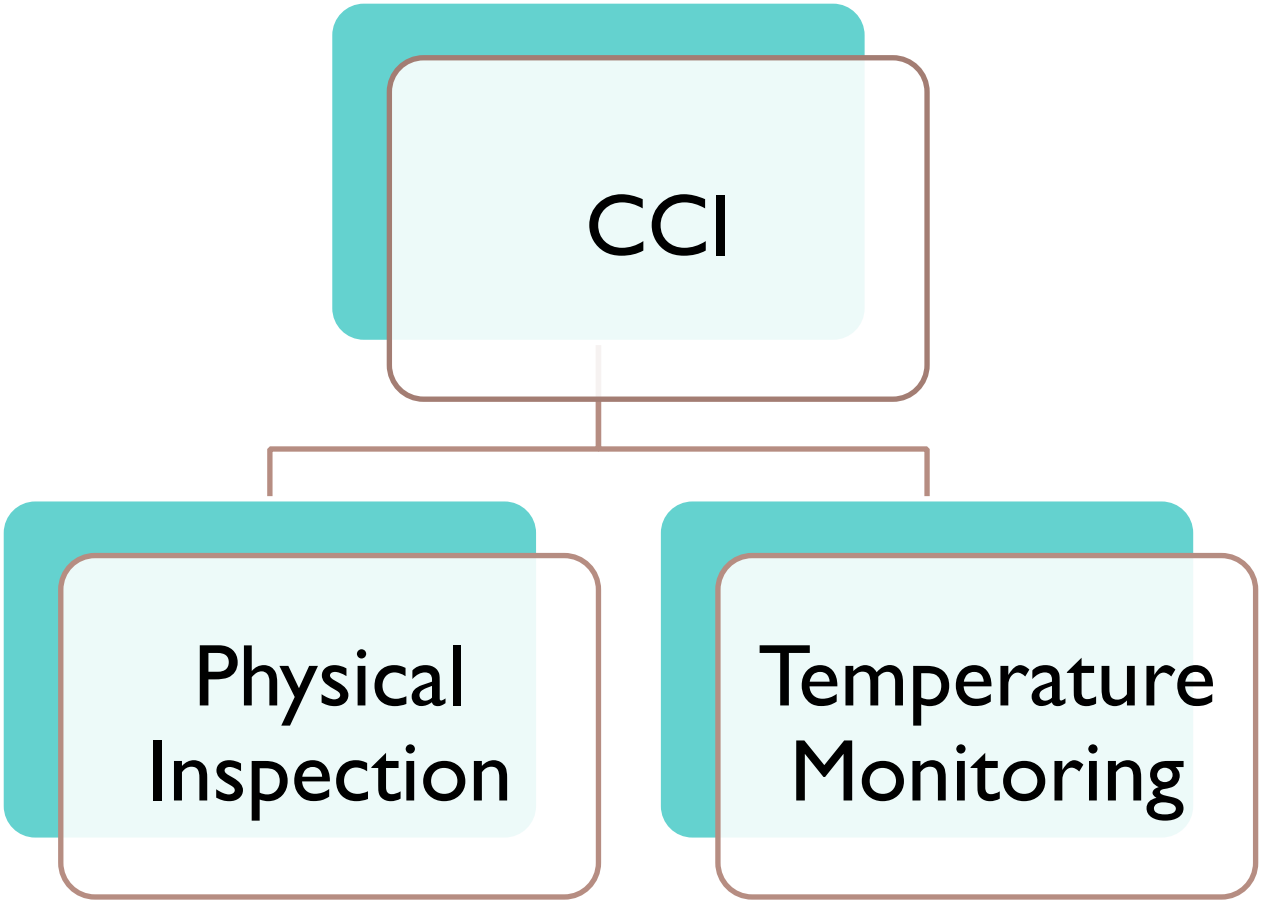


LEGEND:
PRH: Product Registration Holder
CQC: Centre for Quality Control
CCL: Centre for Compliance and Licensing

Timeline For CCI

- CCI to be conducted within 2 Working Days (WD) after product arrival at warehouse (PRH to inform CC Team time of arrival)
- If LSP & CCI are satisfactory, Lot Release Certificate (LRC) will be issued by NPCB within 6 WD after product arrival
- If not satisfactory, Notification of Non-Compliance (NNC) will be issued by NPCB

Cold Chain Inspection (CCI)



Physical Inspection

- Name & Dosage
- Quantity
- Name & address of Manufacturer (based on Application Form)
- Condition of Package
- Seal of Package
- Batch No
- Expiry Date

* Other related documents: Packing List, Airway Bill (AWB), Invoice (if available), Certificate of Analysis (CoA)

Temperature Monitoring

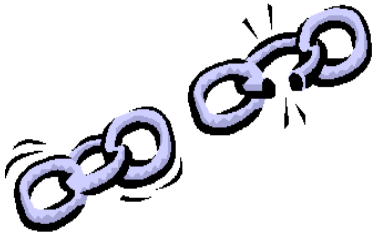
- Type of Container Used (Active system/ Passive system)
- Type of Coolant Used (Ice pack/ Phase Change Material)
- Temperature Monitoring Device Used (TempTale/ Cold Chain Monitoring (CCM) Card)
- Any excursion noticed during the inspection

Other requirements..

- Preliminary inspection on the warehouse facilities (for those that are not involved with Vaccine Lot Release)

  - PRH will be informed by CC Team

- Submission of Packaging and Shipping Validation Report



References

- Guidelines on Good Distribution Practice (GDP) 2nd Edition, 2013. National Pharmaceutical Control Bureau.
- Supplementary Notes for Management of Cold Chain Products/ Materials, Chapter 15 Guidelines on Good Distribution Practice (GDP), 2014
- WHO Technical Report Series, No. 961, 2011, Annex 9 - Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products,
- PIC/S Guide To Good Distribution Practice for Medicinal Products , PE 011-1, June 2014
- Manual on the Management, Maintenance and Use of Blood Cold Chain Equipment, WHO 2005


THANK YOU
for your attention!