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DEVELOPMENT REVIEW GROUP

Notes for a meeting to be held at 2.00pm on 15th October 1986

*9/10/1986*

Projects which currently have a major Production involvement.

1. PLASMA1.1 Quality of Plasma from Machine 'pheresis

Various pools from Aberdeen and Law waiting to be fractionated via final Z8 process and DEFIX process. Major QC involvement in analysing/storing plasma samples.

PROJECT LEADER PERRY

1.2 Plasma Transport

PROJECT LEADER DICKSON

1.3 Plasma Pack Removal

Plasma bags from 2 manufacturers ready to be tested at full scale. Bag from 3rd manufacturer needs further development and testing at small scale.

Machine has been rebuilt but requires more substantial pistons to be fitted. Review of RTC's freezing systems is in progress.

PROJECT LEADER PERRY/FOSTER

1.4 Plasma Conditioning

Effect on cryoppt quality.

PROJECT LEADER DICKSON

2. FACTOR VIII2.1 Introduction of Z8 Process

Requires further developments in formulation and freeze drying to enable heating at 80 °C/72 hr to be achieved reproducibly.

PROJECT LEADER MCINTOSH

3. FACTOR IX3.1 Improving Reliability/Capacity of DEFIX Process

Standardisation of chromatographic steps has been improved by using Wrights column and by using DE52. New basket centrifuge is being

introduced to handle larger quantities of gel. Problems of microbiological quality, low potency and low yield after heating remain.

PROJECT LEADER DICKSON

3.2 FIX Thrombogenicity in Dogs

Production material required for dose response study. Pyrogenic batch available but may compromise study.

PROJECT LEADER CUTHBERTSON

4. IMMUNOGLOBULINS

4.1 Stability of IM-Product

Observations on-going.

PROJECT LEADER MCINTOSH/WELCH

4.2 Production of IV-IgG

Various longer term strategies for increasing/improving production still to be resolved. Dramatic change in protein distribution still to be explained.

PROJECT LEADER MCINTOSH/WELCH

4.3 Anti-Endotoxin IgG

Uncertain following confusion surrounding pilot-scale animal study.

PROJECT LEADER CUTHBERTSON

4.4 McAb Blood Grouping Reagents

To be progressively handed over to Production. Needs careful appraisal of medium - long term requirements.

PROJECT LEADER MACLEOD

5. ALBUMIN

5.1 Fibre Contamination

Observations on-going - may require mix of FFP/outdated. (RIE experience). May be resolved by increasing product purity. Studies underway in R&D.

PROJECT LEADER FOSTER

5.2 Metal-Ion Contamination

Sources of contamination being identified. Studies to improve washing of depth filters underway.

PROJECT LEADER CUTHBERTSON

5.3 Ultrafiltration of Albumin

Strategies for Production under consideration. Further R&D work required.

PROJECT LEADER FOSTER

6. TECHNOLOGY6.1 CSVM Modules

Strategy for best use of 6 modules; various on-going modifications to Scomag module (eg pH mixer)? Commissioning reports for 3 and 6 modules desirable.

PROJECT LEADER DICKSON/WALKER

6.2 Solids Discharge Centrifuge

Requires effort.

PROJECT LEADER DICKSON

6.3 Defining Capacity of Adsorptive (Depth) Filters

PROJECT LEADER DICKSON

6.4 Computer Applications

DBM

PROJECT LEADER WALKER

wahm.

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22/9/86