

S1:MINUTES

Product Dev. Group

Factor VIII
Contract

→ C.V. Prowse

CJDC

MPL/Products

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Minutes of meeting held on Friday 10th November at HQ LaboratoryPresent: D.S. Pepper, C.V. Prowse, P. Foster and I.R. MacGregorAGENDA: FVIII (see attached Appendix)

FIX

Hb

BPS Novel Ion Exchangers (Biotechnology Processing Services)

FVIII

Following considerable discussion of various options listed by DSP (see attached Appendix) the following high priority areas were agreed deserving of joint action:

- (1) Terminal heating (including both dry and wet heat and possibly solvent-detergent) as a viricidal step - empirical and theoretical study of variables (DSP & PF/RM).
- (2) Commissioning of Quadra Beam IR moisture analyser and development of calibration and standards. DSP to liaise with Bruce Cuthbertson and PFL Oxford.
- (3) Assay development including FVIII CAg, Blotting of FVIIIIC chains, vWF multimers, collagen binding of vWF (ELISA), vWF Ag ELISA (jointly CVP/IRM/DSP)
- (4) Existing and novel stabilizers to be studied including Redox potential, thiols and O₂ content (includes common interest with Hb project) (DSP & SMacD)
- (5) HPLC assays for detergents and solvents to be set up (DSP & SMacD)

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SMacD to progress work on viral inactivation of Hb (especially wet heat) and $t_{1/2}$ in rats (with IRM/LMCL) and exchange $t_{1/2}$ (with Belfast). We suggest 3 years to clinical trials as a realistic time

Resource Implications

FVIII A full time person is required for FVIII assay development, additional input is also possible immediately on ELISA (OD) and HPLC (SMacD) and wet heat (SMacD).

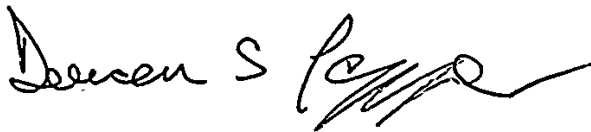
A chamber stoppering freeze-drier is needed for the Super Modulyo with some instrumentation - incl. VAT £ 16,000. Also a platelet aggregometer for RiCof assay.

No other major resources are perceived necessary at this time.

FIX IRM/CVP Resources implication will be appended to the aforementioned proposal

BPS - Ion Exchanger No major resource implications

Hb One major area that needs further discussion (eg. December 14th Hb meeting) is how toxicology/safety should be tackled and hence what cost.



D.S. Pepper

11.11.89