

Headquarters:

: Blood Products Laboratory
Dagger Lane, Elstree
Borehamwood, Herts. WD6 3BX

Plasma Fractionation Laboratory
Churchill Hospital
Oxford OX3 7LJ

Telephone: Direct Line GRO-C
via Hospital 6655-64544

5th April, 1988.

Dr. G. Saraiva de Melo,
Hemope,
Rua Joaquim Nabuco 171,
Recife,
Brazil.

Dear Dr. de Melo,

I have a brief note from Dr. Rizza to the effect that you are interested in having your fractionators make a factor VIII concentrate which is safer from virus transmission than cryoprecipitate. A number of Blood Banks have proposed mild heat treatment of freeze-dried cryoprecipitate, but my personal opinion is that heat treatment below about 68° is not absolutely guaranteed to inactivate a very high titre of HIV, and will certainly not always inactivate NANBH.

Dr. Rizza added that you might wish to consider making a "high purity" concentrate like our 8Y. I attach a diagram of the process. Details sufficient to operate the process have not been published, are the subject of world-wide patent applications, and can be divulged only under cover of a Confidentiality Agreement with our administering authority, the Central Blood Laboratories Authority. If you would like further information, please write to Dr. R.S. Lane, Director, Blood Products Laboratory, Dagger Lane, Elstree, Herts., stating who would be responsible for a decision to manufacture in Brazil, and their commercial or non-profit status, etc., since manufacturing would ultimately involve licensing.

The 8Y process is used routinely at Oxford on the 300 kg scale and at Elstree on the 3000 kg scale, but smaller pilot scale is worth considering. The main changes from single-donor cryoprecipitate production would be learning to make cryoprecipitate on the large scale, using large continuous-flow centrifuges, maintaining hygienic precautions in "open" processing, and focussing on the finer requirements for freeze-drying a product which is to be severely heated. Even if your fractionation plant is already expert in the production of e.g. IgG and albumin, adjustment to a large-pool factor VIII concentrate would almost certainly require some familiarisation and training in one of our fractionation centres. I am sorry that I do not know more about your fractionation arrangements in Brazil, but I hope this will give you some indication that moving up from single-donor cryoprecipitate is quite a serious and expensive step.

Yours sincerely,

J.K. Smith
Chief Project Scientist.

cc. ✓ Dr. R.S. Lane.

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