

S P E Y W O O D L A B O R A T O R I E S L I M I T E D

MINUTES OF THE OPERATIONAL MANAGEMENT MEETING
HELD ON WEDNESDAY 31ST OCTOBER AT 10.00A.M.

Present : Dr. W.E.Lewis
 Mr. D.W.Wain
 Dr. D. Heaf
 Dr. P.N.Robinson
 Mr.C.C.Ilott
 Mrs.A.Morton
 Mr. J.W.Savage
 Mr.D.Jones
 Mrs.M.Poole (Secretary)

MINUTES OF PREVIOUS MEETING

ACTION

It was agreed by the Committee that the Minutes of the previous meeting be accepted. However, Mrs.Poole was asked by the Committee to submit a draft of the minutes to each committee member for their approval before being tabled and accepted at the Committee Meeting.

MP

NEW ITEMS

9. WEL asked that CCI's report on Regulatory Affairs be brought forward to the beginning of the meeting as the F & D A Regulations and proposed Product Licence should be in the foreground of our thinking in future and affect the running of each department.

10. CCI reported that the UK Product Licence was now being signed and it would probably be in our hands within a fortnight. Once the Product Licence is signed we shall have to submit our Data Sheet.

An Export Licence and Certificate of Free Trade may mean a quicker entry into Europe rather than await each Country's own individual requirements for Product Licence.

CCI stressed Brian Mullocks remark whilst visiting Speywood last, that our ideas and plans were "excellent" but our

facilities for production and control "a disaster area". Brian Mullock was to have started a training course on GLP for QC and R & D in conjunction with DH, unfortunately BM has postponed his session for a short time but DH to start his course on the 9th November.

CCI stated that Graham Blake is to start routinely controlling "Equipment Usage".

He reported that a training programme is under development for the abattoir. This is to act as a basis for other departments.

The security of abattoir documents and production records was discussed. It was noted by the Committee that there was a definite need for more security as any Licensing Authority would not tolerate loss of documentation. It was suggested that we have a Records Office and this is now to be looked into re-location and staffing by WEL/CCI.

CCI informed the Committee that the DHSS looked more favourably on companies who kept their work "in-house" rather than parts of the process or testing being located elsewhere.

CCI enquired as to the basis for Clinical Trials as the information gained on each patient when under treatment by Hyate:C must go towards the data to be sent for F & D A Licence. Therefore, each patient must be chosen carefully otherwise any adverse information will go against us. If a patient is so ill no other treatment is likely to work then we are taking too much of a risk including it as a clinical trial as the data may work against us.

CCI expressed the need to support any further Licence applications with experimental evidence validating production and QC methods.

11. PNR opened his report on Plasma production by stating that finding staff at the right level of ability for the salary stated may be difficult. We require a person with supervisory skills for Godley but our wage structure is such at the moment that the salary offered is not good.

PNR is still looking urgently at alternative sources of blood collection as he feels the pig market is depressed and we must have a contingency plan in case of the failure of either of our abattoirs to continue supply. Mr. Gert Johanssen of Ellco, Sweden is visiting Speywood during November and PNR is looking closely at this company as an important alternative source of blood collection.

Negotiations with Christian Salvesen on bulk storage and insurance are going well. DW/PNR to ensure our continued presence at Christian Salvesen.

12. JWS reported on processing at Wrexham. He was pleased to inform the Committee that the three new members of staff are proving to be very suitable.

He stated that there was a drop in Plasma collection which would eventually make its presence felt in production if we wish to keep our production to 1Mu per month.

JWS said freeze-drying was currently an area of concern. CP Pharmaceuticals are now testing a new product and may wish more use of the freeze-dryer, this will inhibit our use.

It was suggested by the Committee that JWS seek out ways and means of moving into our own Envair Suite with in-house freeze-drying then in mind. The Committee felt we must prepare ourselves for the future by spending properly now in readiness for F & D A approval.

DW enquired as to the figure JWS stated in his production Report for Yield/Filtration. These figures differed from AM's figures in QC report. AM/JWS to get together to re-check figures.

WEL said if the yield was paramount with plasma limited it was therefore permissible to keep plasma back rather than run and wait for better batch of polyelectrolyte for example which would increase yield.

13. AM began her report on QC by informing Committee that she and our technical Consultant (Mrs. S. M. Middleton) had

visited Dr. Trevor Barrowcliff at NIBSC in collaboration with producing an international Porcine VIII:C Standard, and to discuss the on-going standardisation of our present VIII:C unit. Trevor Barrowcliff is well noted in his profession as an expert on assay work and it is hoped he may be invited to Wrexham to give his advice on freeze-drying and on the statistical analysis of stability data to predict long term storage on a standard. It would be a useful idea for this meeting to be arranged before our next in-house Standard, HY85, is prepared.

Staffing levels were mentioned again by AM. Microbiology Department need at least one more member of staff as BT does not get enough time to visit the abattoirs regularly to monitor environmental control and test for bacterial contamination in blood at source and during collection.

Graham Parry was now transferred to QC and was helping GB in his work.

Mrs.V.Smith, who was employed a short while ago has resigned as she has been offered other employment at a higher salary. Therefore the clotting lab is now still short of 1 member of staff and although staff can be trained to do assay work, a person of high ability is required for a greater understanding of the basis of the assay work, and hence the need to entice the correct type of person by adequate remuneration is very important.

14. As a Chief Engineer has still to be appointed, WEL once again filled this position.
- He stated that Mr. A. Beattie was to be asked to join us after interview, for the post. However
- 1) ICI and UMIST are short staffed therefore it will be three months before he can join us, and
 - 2) Mr. Beattie does not wish to move to Wrexham and therefore has requested a three month trial period to prove to us that he can manage to travel from Altrincham to Wrexham and still supervise to a high level.
- WEL felt that if he was prepared to give us three months trial period he must be keen to commit himself to the position.

WEL mentioned that Mark Davies was proving very suitable in the Engineering Department but that we would still need to find an Engineer of the level of David Owen to take over very soon.

He said that due to badly designed equipment the Engineering Department had a very difficult job to do, but he said once we have good staffing levels and improved equipment the running of the Engineering Department must be much more smooth.

15. DJH spoke of our need for another source of Polyelectrolyte as mentioned in his report. Fisons are making a great effort to overcome their problems in producing Polyelectrolyte and he was very impressed with Peboc in their efforts to do the same. Altogether quite a number of firms have expressed an interest in making Polyelectrolyte and it looks hopeful.

Janice McCreedy, our new member of staff in R & D is working full time on the Polyelectrolyte project. Also working for R & D on a one-year Sandwich Course with Hatfield Polytechnic is Sean O'Brien. DH stated that MR. O'Dell one of Sean's tutors had asked if it would be possible for Sean to gain experience in other Departments of Speywood and it was put to the Committee that this was looked into as a possibility.

Over the next few months DH said Pat Ashton was looking into final product protein profile, data and pig facts all in relation to information which will be required by F & D A when a Product Licence is sought. PA may need to get together with CCI as he will eventually require this information. Mary White is very involved at the moment with the freeze-drier working for different projects which require the product to be freeze-dried.

DH said he was worried about certain safety aspects within the Company. For instance, the storage of solvents and gases. It was suggested by the Committee that this should be looked into - DW to meet with DH to discuss a strong storage room preferably off the factory site.

In relation to the above WEL asked if there had been any progress with the Safety Committee. DW stated that he, CCI, DJ and JWS were to get together to seek out any problems within the factory.

16. DW started his report to the Committee with the good news that over £100,000 worth of Hyate:C had been sold in September and £162,000 had been sold in October. He said that as Porton International's year ending for accounts was June, we must now come into line with this and asked that all Heads of Departments prepare their budgets before the end of the year as he will now have to go to Porton International with Speywood's overall budget. Heads of Departments will only budget for six months to meet with the June Porton end of year deadline. DWW will issue budget sheets.
17. It was decided that the next meeting of the Operational Management Committee will be November 23rd. If this date is to be changed due to Brian Mullock's visit all members of the Committee will be duly notified.
18. JWS asked if a copy of the Minutes of the Works Forum Committee could be tabled at each meeting of the Operational Management Committee. It was agreed that they would be circulated to the Management Committee.
19. It was suggested that a list be prepared each Friday stating the whereabouts of each Committee member for the following week. This was to be the responsibility of Merys Swinnerton who would circulate same. DW to inform her.
20. The meeting ended with the agreement that a much better knowledge of each individual department had been gained by all members and therefore much more understanding between departments.