U.K. Radiopharmacy Group

NEWSLETTER
2005 Q3

The July 2005 meeting of the UK Radiopharmacy Group was held at Aston University, Birmingham. Items of general interest are summarised below.

UPCOMING UKRG EVENTS

UKRG Workshop 2006

The next workshop will take place on Friday 13 January 2006 in Bournville, Birmingham, and all non-superstitious radiopharmacy types are welcome. The full programme and registration information will be available shortly on the UKRG web site, but the topics include radiochemical purity testing and radiation safety aspects of ^{90}Y-Zevalin preparation. The afternoon will be taken up with the popular and athletic Controversy Corners, with topics including radiochemical purity testing, MAA particle numbers, deviations from manufacturers' instructions, syringe shield policies, and manual handling aspects of generators. It promises to be a good day so we hope to see everyone there. For further information or questions please contact paul.maltby@rlbuht.nhs.uk.

Postgraduate Course in Radiopharmacy

The annual course at King's College London will be run during the week of 13 March 2006. More information will be available shortly. In the interim please contact jim.ballinger@kcl.ac.uk.

WORKFORCE ISSUES

Agenda for Change

The banding for the Principal Radiopharmacist/ Radiopharmaceutical Scientist post at Guy's and St Thomas' Hospital London was revealed in August: band 8c. The job was matched with the national profile for Pharmacist Team Manager with a score of 642 points and matched on all 16 factors.

National occupational standards / Career pathway

A summary and the full text of all 581 healthcare science National Occupational Standards are now available on the Skills for Health website: http://www.skillsforhealth.org.uk/view_framework.php?id=73. The KSF links have not yet been made but are being worked on centrally and may be added in September. The radiopharmacy standards are HCS_R1 thru R15. Other relevant standards include nuclear medicine (HCS_NC), medical physics (HCS_MPHYS), and radiation protection (HCS_RP).

Technologist/scientist HPC registration

As compulsory registration comes in, the lack of a defined pathway to registration in radiopharmaceutical science will become acute. Anyone not registered would only be able to work under supervision. This would pose a problem for new people coming in, e.g. from abroad, and will be a particular problem for PET. The HPC grandparent route has closed and the clinical technologist voluntary register will close next year, after which there will be a requirement for a degree. The IPEM technologist training scheme is under review and it might be possible to incorporate radiopharmacy techs.

REGULATORY ISSUES

Clinical trials / Investigative medicinal product (IMP) licences

There continues to be an enormous degree of confusion over this issue (to quote the opening sentence from the two previous Newsletters). The issue of Qualified Person (QP) for release of IMPs is emerging as a serious one, since the grandparent provision expires May 2006. A full QP course is extremely expensive and time consuming and it seems unlikely that anyone from radiopharmacy would be prepared to make that commitment, particularly within the NHS. As an alternative to having an on-site QP, the results of analysis can be sent to an off-site QP electronically, or a contracted QP could be used.

Another issue which is emerging is the requirement for an IMP quality system which is separate from the GMP quality system already in place for specials licences. It is recommended that units audit themselves against Revision 1 of Annex 13 on the MHRA web site (Annex 13 in the Orange Guide is now out of date). One difference from GMP is the role of the sponsor and the lines of accountability. Some of these issues will already be captured in the Trust R&D office.

Other differences from GMP: There are no specials under IMP licences. The QP is required to certify that the product complies with the product specification filed with the MHRA. Before a trial can commence, all agreements must be in place, the details of the sponsor must be known, approval from relevant bodies must have been received, and there must be a procedure for receiving of orders and release of products. Clinical trials materials must be segregated and logged in and out. It is a very complex system.

Radiopharmacy computer systems

The Veenstra product through Bright Technologies is being beta tested at two centres in the UK. However, this requires the Veenstra dose calibrator.

The Radiopharmacist's Friend, an Excel-based system which supports radiopharmaceutical preparation, stock control, and printing of worksheets, labels, and transport documents, was developed at Bart's. It is intended to be distributed as freeware via the VirRAD web site for local customisation and implementation, with the modifications to be fed back and shared. However, it is only a tool and must be validated locally.

One of the vendors of radiology information systems has promised a radiopharmacy module but it has yet to appear.

MHRA inspections

Some issues which have come up during recent MHRA inspections of licenced units include:

- The use of paper rather than laminated labels on vials. The UKRG is not aware of any problems associated with this.
- One inspector commented that separate facilities would be required for antibody labelling, referring to the revised Annex 1 regarding products of microbiological origin. The UKRG has discussed this previously and recommends that a risk assessment be done before commencing work with antibodies.
- The frequency of particle monitoring. It is recommended that there be a local agreement with the quality controller. Obviously, the frequency would depend on the type of work performed.
- One inspector commented on sterility testing. The BP test procedure cannot be used because batch sampling is not possible and bacteria may die during decay because of self irradiation or the lack of nutrients in a kit formulation. Addition of double strength broth to a kit residue with a positive control may be sufficient, although thorough sanitation afterwards would be required.

PRODUCT NEWS

DMSA kits

GE/Amersham has announced that they are withdrawing DMSA kits from the market with immediate effect. The only DMSA kit with a UK product licence is Renocis from Schering.

DTPA kits will also be withdrawn next year. There are at least two licenced alternatives on the UK market.

Leukoscan

Leukoscan is currently off the market while Immunomedics awaits official approval of their revised marketing authorisation due to a change in manufacturing facilities.

UPCOMING MEETINGS

International Conference on Radio-pharmaceutical Therapy

11-14 October, Cyprus. See VirRAD web site.

International Symposium on Trends in Radiopharmaceuticals (ISTR-2005)

14-18 November, Vienna. Further details available on the UKRG and VirRAD web sites. Registration is free but applications must be channelled via the appropriate government agency. For those in the UK this is:

Export Control and Non-Proliferation
Department of Trade and Industry (DTI)
4 Abbey Orchard Street
London SW1P 2HT
United Kingdom
Tel 0207 2150720
Fax 0207 2150722

European Symposium on Radio-pharmacy and Radiopharmaceuticals

30 Mar-2 Apr 2006, Pisa. First announcement is out. Contact: info@eanm.org.

UPCOMING COURSES

Postgraduate diploma course (PDC) in Radiopharmaceutical Chemistry/Radio-pharmacy

Consists of three 2-week blocks over one year, next offered in February 2006, held in Frankfurt, Zurich, and Leipzig. See VirRAD web site.

MSc in Radiopharmaceutics and PET Radiochemistry

King's College London, beginning September 2005. One year full-time or two years part-time (day release). The course is starting with eight registrants.

Semester 1:

Module 1, Introduction to radiopharmaceutics

Module 2, Radiopharmacology

Semester 2:

Module 3a, Radiopharmaceutical chemistry

or *3b*, Radiopharmaceutical design, formulation, and manufacturing

Module 4a, Cyclotron engineering and nuclear chemistry (with 2-week cyclotron placement)

or *4b*, Radiopharmaceuticals in practice (with 2-week radiopharmacy placement)

Semester 3:

Module 5, Research project

For further information please contact:
anthony.theobald@kcl.ac.uk

The UKRG is offering a bursary of £1000 toward the cost of the course for an NHS employee who has been unable to obtain full funding elsewhere and who agrees to remain within the NHS for at least two years after completion of the degree. For information please contact:
paul.maltby@rlbuht.nhs.uk

It is anticipated that in the future individual modules will be offered for credit.

UKRG HANDBOOK

The group spent the day in advance of the July meeting reviewing the handbook and assigning tasks. It is hoped that the revised handbook will be available on the web site early in 2006.

PEOPLE

The UKRG welcomed ***Ann Richardson*** from Leeds who will represent the region in tandem with Barbara Wensworth from Bradford. We also welcomed ***Sue Ackrill*** from Birmingham as a permanent member.

Tony Theobald retires from King's College London in September. He was involved in the education and training of much of the radiopharmacy community in the UK. However, his retirement to Shropshire has been delayed for a year, as he will be co-ordinating the new MSc programme in radiopharmaceutics and PET radiochemistry at King's.

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