

UKRG EVENTS

Summer school in radiopharmaceutical quality control techniques

Under the auspices of UKRG, King's College London will be holding a 2-day summer school offering lectures and practical experience in radiopharmaceutical quality control techniques. It will be held at the Waterloo campus of KCL on 17-18 July and full details can be found in the accompanying brochure and are on the UKRG website. We have had financial support from LabLogic and PerkinElmer so far, and most of the radiopharmaceutical suppliers have donated kits. Please contact jim.ballinger@kcl.ac.uk if you require further information.

UKRG INITIATIVES

Hetastarch

Hespan is still unavailable. The last issue of the Newsletter described some alternatives, though none is completely satisfactory. The UKRG is working with an NHS manufacturing unit to supply hespan from a European source but this is still a number of months away. Watch this space.

Back-up supply of ^{99m}Tc

Recent problems with generator supply have raised the question of a co-ordinated approach to back-up supply of ^{99m}Tc pertechnetate. In the coming months the UKRG will compile data on who uses which manufacturer's generator in an attempt to organise regional networks for back-up supply in the event of one vendor having a production failure.

Problems reported with radiopharmaceuticals

In the first quarter of 2008 there were 14 reports submitted to the UKRG / BNMS / EANM registry. Eight of these were a variety of minor reactions to MDP, HDP, or DMSA. Two involved failure to label – MUGA and tetrofosmin (the latter incident

prompted the advice in the last issue of the Newsletter). One concerned a generator which failed to elute. The final three were from the same unit and concerned an apparent wet bed phenomenon on the first elution of a mid week generator; in each case the yield rebounded the following day but no causal factor could be identified by the manufacturer.

IPEM

A representative from the UKRG attended a meeting of the nuclear medicine special interest group of IPEM. Among the topics discussed were technologist training and registration. It was resolved to increase communication between the two groups, including sharing of Newsletters and advertising of events such as our Bournville workshop.

REGULATORY ISSUES

A new professional body

Pharmacist members among us will certainly know that the functions of the Royal Pharmaceutical Society of Great Britain are to be split, with the regulatory aspects devolved to the General Pharmaceutical Council and the formation of a new professional body, possibly to be called the Royal College. A year or so ago a group of specialties within pharmacy concocted the Waterloo Agreement, named for the neutral location where the meeting was held. In the interim, the report of the Clarke enquiry into the future of pharmacy has been published and letters are flying left and right in the Pharmaceutical Journal.

However, this is not solely of interest to pharmacists, because membership in the new body will (almost certainly) be open to non pharmacists (partly because they will need the income from non pharmacists to make it financially viable). The UKRG has been part of the Waterloo group and are looking to this new professional body as being something that anyone involved in radiopharmacy can join, regardless of their route into the profession. There is also the intention that technicians would be members.

Feedback from MHRA inspections

Among the topics which featured in recent inspections of licensed units are:

- Management level support for capacity and resource issues.
- Service level agreements with contract QC labs (e.g. micro) coupled with actions based on results from the labs.
- Service level agreements for planned preventative maintenance of facilities and equipment.
- Checking and release of batches should be performed by someone independent of production on that day.
- For new builds, validation of the finished build against the original specification and a log of changes during construction. This problem tends to be worse with PFI builds.
- SOPs for unlicensed kits to include confirmation of TSE status and notification of ARSAC holder.
- Regular formal review of product package inserts.
- Separate SOP for release of IMPs by QP.
- Evidence of training to include proof of competency and assessment of underpinning knowledge
- Sessional finger dabs in class A workzones.

QP-IMP

Thanks to lobbying by the UKRG, the imminent problem of a lack of QPs for IMPs and the stifling effect this will have on clinical trials, which we have been banging on about for several years, has finally made it onto the radar at the PET Steering Committee, the Royal Colleges of Physicians and Radiologists, the Cancer Czar, the Pharm Soc, and the Chief Pharmaceutical Officer. The objective is to bring UK regulations in line with those in Europe where IMPs can be released by authorised radiopharmacy specialists. Again, watch this space.

INDUSTRY NEWS

Hepatate unavailable

Tin colloid (Hepatate, GE Healthcare) is currently unavailable due to the need to validate a new supplier of the active ingredient, stannous fluoride. The product could be off the market for as long as a year. ARSAC has been informed and will expedite applications for the use of pertechnetate in place of colloid in lacrimal drainage studies. Polatom makes a similar product which can be imported as a special. However, its use as a solid phase marker for gastric emptying studies has not been validated

and, as attested by recent discussion on VirRad, could be a problem.

Stannous agent unavailable

Stannous medronate (Stannous agent, GE Healthcare), used for pretinning for *in vivo* red blood cell labelling, is currently out of stock due to a surge in demand depleting stocks. There are two alternative agents with full UK product licences: PYP (Covidien) and Angiocis (Qados). However, their tin content and final concentrations are different so the directions for administration will need to be altered.

⁵¹Cr-EDTA unavailable

There is a short term unavailability of this agent (a hat trick for GE Healthcare). ^{99m}Tc-DTPA can be used as a licensed alternative. Polatom also make ⁵¹Cr-EDTA and this can be imported as a special.

Long term ⁹⁹Mo supply

You will recall that last December there was an international shortage of ⁹⁹Mo due to a temporary shutdown at the reactor in Chalk River, Ontario, which produces 60% of the world supply. The Canadian government passed legislation within a day allowing the reactor to resume operation despite safety breaches. The reactor is some 50 years old and was due to be replaced by two new production reactors. However, it has recently been decided that the new reactors, which are years behind schedule, well over budget, and distinctly dodgy, are to be abandoned and the current reactor will be decommissioned in a couple of years. Thus, there is a scramble to find alternative sources. While this may not directly affect the UK, it will certainly affect the nuclear medicine community as a whole.

MEETING REPORTS

BNMS Annual Meeting in Edinburgh

The recent BNMS annual meeting was a great success. Attendance was good, the conference venue excellent, and the city as spectacular as ever. There were two invited talks in the area of radiopharmaceuticals. Phil Blower from KCL gave a talk entitled "Radiopharmaceutical chemistry: the challenges ahead". Greg Mullen, also from KCL, spoke about cell labelling – how techniques we have been using for 25 years can be directly applied to track stem cells or genetically modified cells.

In terms of practice based presentations, the Glasgow group looked at hepatic uptake of ^{99m}Tc DMSA from different manufacturers; ironically, the worst performer is the only UK licensed product.

Not to be outdone, the Edinburgh group showed that the rate of complexation of ^{99m}Tc with mebrofenin is dependent upon concentration; for best results the kit should be reconstituted in 1 mL pertechnetate and incubated for 30 minutes before dilution for use.

Radiopharmacy fared well in the awards. First prize for student presentations went to Amanda Weeks, PhD student at Kent, "Hypoxia-targeted radionuclide therapy: hypoxia-selective toxicity and DNA damage induced by ^{64}Cu -ATSM". First prize for oral presentations went to Rowena Paul, post doc at the St Thomas' PET Centre, "Routine availability of ^{61}Cu and ^{64}Cu for clinical PET applications".

I was very impressed by the conference centre. It looks brand new but is apparently 10 years old. Its high tech features include the ability to rotate the balconies of the main auditorium into separate conference rooms.

European Symposium on Radiopharmacy and Radiopharmaceuticals

I hope to have a meeting report in the next issue, if someone will volunteer.

UPCOMING MEETINGS

Society of Nuclear Medicine annual meeting 14-18 June, New Orleans. www.snm.org

Probe Development in Molecular Imaging and Therapy American Chemical Society, 17-21 Aug, Philadelphia. www.acs.org

World Molecular Imaging Congress 10-13 Sept, Nice, France. www.wmicmeeting.org

British Nuclear Medicine Society autumn meeting 25-26 September, Liverpool. Abstract deadline: 27 June. www.bnms.org.uk

National Cancer Research Institute 5-8 October, Birmingham. www.ncri.org.uk

European Nuclear Medicine Congress 11-15 October, Munich. www.eanm.org

7th International Meeting on the Effects of Low Doses of Radiation in Biological Systems: New Perspectives on Human Exposure 27-29 Nov, Lisbon <http://www.lowrad2008.itn.pt/>

From the Editor

This was my third visit to Edinburgh and it remains one of my favourite cities. I had the full Scottish experience: haggis for breakfast (vegetarian – does that count?), my first taste of single malt whisky (not at breakfast) – an ounce cost as much as I would usually pay for a bottle of wine (which probably says more about my choice of wine). It is the home of two of my favourite writers, Conan Doyle and Ian Rankin, and we went on walking tours of their haunts. We saw *both* of the JK Rowling cafes and took photos to keep our nieces happy. I also enjoyed meeting the delightful members of the UKRG Newsletter Fan Club based at the Edinburgh Royal Infirmary!

www.ukrg.org.uk

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