

UKRG INITIATIVES

UKRG Radiopharmacy Workshop 2011

The annual workshop was held in Bournville on Friday 14 January with a capacity crowd (and the largest group ever at the curry house the night before). A summary of the sessions appears later in this Newsletter.

Postgraduate Course in Radiopharmacy

The course ran 14-17 March at Guy's Hospital with 25 in attendance. Thanks to the many speakers from the UK Radiopharmacy Group.

BNMS annual meeting, Brighton

The radiopharmacy sessions take place on Tuesday 10 May. Invited speakers will address Clinical applications of radiolabelled nanoparticles, Safe administration of radiopharmaceuticals, Practical aspects of using ^{68}Ga generators, and ^{99}Mo supply: today and tomorrow. There will be 7 oral presentations. There will also be the annual meeting of the BNMS radiopharmaceutical science group.

Storage of Draximage MDP kits

With GE Medronate kits not being currently available, a number of radiopharmacies have been purchasing Draximage MDP kits from Guerbet. The storage instructions for the kits say "Do not refrigerate or freeze." This is because the manufacturer did not submit any stability data obtained at 5°C to the regulatory authorities. However, several UK radiopharmacies have anecdotal evidence that there is no problem with storing the kits in the refrigerator.

Unusual biodistribution/product defects

A compilation of the reports submitted in the calendar year 2010 should accompany this Newsletter. The monitoring scheme is co-ordinated by: neil.hartman@bartsandthelondon.nhs.uk

Sampson's Textbook of Radiopharmacy

The fourth edition of the textbook, this time edited by Tony Theobald, was published in December by the Pharmaceutical Press.
www.pharmpress.com

MOLYBDENUM

Strategic report to Department of Health

The National Imaging Board commissioned ARSAC to prepare a report and recommendations on the medium term response to the molybdenum situation. That strategic report, which endeavours to ensure the stable supply of $^{99\text{m}}\text{Tc}$ labelled products to nuclear medicine, may have far reaching effects on the practice of radiopharmacy. The report appeared on the ARSAC website last December. www.arsac.org.uk

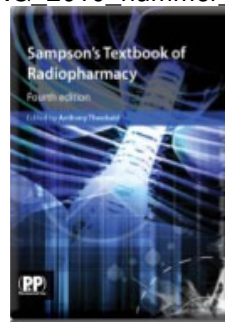
Upcoming problems?

The Chalk River reactor will be closed for planned maintenance in the spring, but the UK suppliers have assured their customers that there will be no impact here.

Covidien has also warned of a potential problem which might have an impact a year from now due to "challenges" in preparation of highly enriched uranium ^{235}U targets for the Petten reactor. However, it is anticipated that this problem will be resolved. Petten is also adapting to the use of low enrichment ^{235}U targets, as was done recently at the South African reactor, but this will require a new processing line in order to handle the larger volumes.

Dutch Journal of Nuclear Medicine: special issue

The Dutch Journal of Nuclear Medicine has produced a special issue on molybdenum shortages. The articles are in English, the adverts in Dutch. To download the pdf go to <http://www.nvng.nl/nvng/index.php?page=tvng> and choose TvNG 2010 nummer 4.pdf



REGULATORY ISSUES

Recent MHRA inspections

Issues which have come up in recent inspections have included:

- External contractors who do airflow monitoring and fail to communicate defects to Heads of Department. This has occurred several times in PFI hospitals using external contractors, so that HEPA filter leaks and other problems are not rectified.
- Inspection of a new PET site demonstrated deficiencies in the quality of the validation work. There were no specialist personnel to carry out the validation, which was insufficient, and the results were poor. However, this was detected at an early stage, so that new validation protocols were written and the work carried out properly.
- Inspection of an existing PET site resulted in one major deficiency as the unit is old and the facility is not up to modern specifications. Corrective action on the walls and ceiling was required. There were comments on the level of QA/QC support, continuous particle monitoring, and process deviations.

PET ligand meeting

On 15 February a meeting was held between the MHRA and representatives from the UK PET research network to discuss the barriers to clinical trials. There were three UKRG committee members present.

Elaine Godfrey began by reviewing the legislation which applies to clinical trials. This was followed by a description of the requirements for the IMP dossier. Ian Thrussell spoke on GMP aspects and there was discussion of nonclinical (ie. preclinical) testing requirements.

Is it a clinical trial? As far as I can see, this is no clearer even after several years. The MHRA have published scenarios but many of them seem to come to the opposite conclusion than I would have. Indeed, it is very difficult to word the research question in a way which avoids being classed as a clinical trial yet yields useful information about the radiotracer.

There was also discussion of the requirements for toxicity studies. A useful distinction was made: the studies need to be done under GLP (Good Laboratory Practice) but not necessarily by a commercial GLP lab. This has led to enquiries about the possibility of finding a public sector lab which could provide these data to GLP standards. The cost of toxicity testing is a major impediment to the clinical evaluation of potential radiotracers.

MEETING REPORTS

UKRG Radiopharmacy Workshop

The title of this year's workshop was "PET, practice, and errors update", a bit of a grab-bag if I ever saw one. The inimitable Tim Sizer started out with "Technical agreements and SLAs – what's the difference?" which told us as much as we would ever like to know about this topic. Then Jo Harper from the MHRA spoke on "Pharmacovigilance and radiopharmacy", a presentation she had given to the committee a year earlier but now shared with a wider group. It struck me that there is a fundamental split within the MHRA: the pharmacovigilance (PV to the initiated) people talk about actual risks while the inspectorate talk about theoretical risks. Jilly Croasdale then discussed the updated guidelines for quality assurance in radiopharmacy; we had originally hoped to launch the updated guidelines at this meeting but this has been delayed for a few months till we have full agreement from the NHS Pharmaceutical Quality Assurance committee.

There were two talks under the PET banner. Rob Smith from the Wolfson Brain Imaging Centre in Cambridge spoke to the topic "From research tracer to GMP production", describing the hurdles in translating the chemistry from a research lab set-up to something which will satisfy the inspectors. Finally, Jim Ballinger waffled on the topic "The gallium-68 generator: is it ready to replace technetium-99m?" By this time we were ready for the usual hearty lunch, which didn't disappoint!

As an introduction to the afternoon syndicate sessions, Richard Bateman reported on "The importance of error reporting: the story so far for CIVAS". The national programme has been running since 2004. It is interesting to look at the error rates: in process, 0.49%; released product, 0.02%; administered product, 0.002%. I would suspect that the in process rates are probably higher for radiopharmaceuticals, partly because we can measure the content so easily. Radiopharmacy has been slow in integrating with this reporting system. The afternoon sessions looked at capturing error data in radiopharmacy. The outcome of the syndicate sessions will be reported in the next issue of the Newsletter.

Marie Curie and Aspects of the History of Radiochemistry

The Royal Society of Chemistry, adjacent to the Royal Academy of Arts in Piccadilly, hosted a one day symposium on 18 March organised by its Radiochemistry and History groups. There were opening remarks from the acting ambassador of France, who then had to rush off and deal with

Libya. The keynote lecture was entitled "Marie Curie: a passion for science, action, and people" given by Dr Serge Plattard, Science and Technology Counsellor at the French Embassy (a nuclear scientist who became a diplomat). We have all heard parts of the story of the life of Marie Curie, but his presentation gave a fuller picture. A truly remarkable person, whose impact went far beyond the discoveries we all know. The Curies were the first to evaluate the biological effects of radium. During the 1914-18 war, Marie Curie designed mobile X-ray units to bring diagnosis to the front line, and trained nurses to operate them.

The next speaker was Prof Alan Dronsfield from Derby, who talked about the early use of radio-nuclides in medicine. And beyond medicine, with all the quack remedies. Later speakers addressed the contributions of Ernest Rutherford, the establishment of Harwell, and the trans-actinides. It was a fascinating day.

INDUSTRY NEWS

Product shortages at GE

Medronate kits have been off the market for several months, with no return date in sight. The only other licensed MDP comes from Draximage and is distributed by Guerbet.

GE has transferred the rights to Stannous agent to Mediam, as was done with Hepatate last year. Mediam hopes to reintroduce Hepatate soon.

From the Editor

Molybdenum supply more or less stable, for the moment. Newsletter out on schedule (just). The year is starting off well. Hope to see everyone in Brighton and Birmingham.

UPCOMING MEETINGS

Becquerel Medal Symposium in honour of Professor Helmut Maecke

Royal Society of Chemistry Radiochemistry Group.
4 April, London. www.rsc.org

Positron Emission Tomography (PET) Technology and Application

13-15 April, King's College London.
www.sthpetcentre.org.uk/petcourse

BNMS spring meeting 8-11 May, Brighton.

Radiopharmacy sessions on Tuesday.
www.bnms.org.uk

Society of Nuclear Medicine annual meeting

4-8 June, San Antonio, Texas. www.snm.org

6th European Molecular Imaging Meeting

European Society of Molecular Imaging
19-21 June, Leiden, the Netherlands.
www.esmi2011.eu

1st World Congress on Ga-68 and Peptide Receptor Radionuclide Therapy (PRRT)

23-26 June, Bad Berka, Germany
www.1stworldcongress-ga-68.de

19th International Symposium on Radiopharmaceutical Sciences 28 Aug – 2 Sep, Amsterdam.

www.isrs2011.org

7th International Conference on Isotopes

4-8 September, Moscow.
www.isotop.ru/en/events/description-event/

European Nuclear Medicine Congress

15-19 October, Birmingham.
Abstract deadline: 11 April. www.eanm.org

4th International Conference on Radiopharmaceutical Therapy (ICRT-2011)

World Association of Radiopharmaceutical and Molecular Therapy (WARMTH), 28 Nov – 2 Dec, Ho Chi Minh City, Vietnam. Abstract deadline: 27 July. www.icrt-2011.warmth.org

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Editor: Jim Ballinger
Department of Nuclear Medicine
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond, London, UK, SE1 9RT
Phone: 020 7188 5521; Fax: 020 7188 4094
E-mail: jim.ballinger@kcl.ac.uk

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