

UKRG INITIATIVES

Adverse Reactions and Unusual Bio-distributions / Product Defects

This database is managed by Neil Hartman at Barts Hospital. Newsletter readers may have noticed the absence of database reports in the recent past; this is because of some technical issues concerning an old version of the database software (MS Access) which are being resolved. Please continue to submit reports of any adverse reactions or unusual biodistributions / product defects via the BNMS or UKRG websites from where they will be forwarded to Neil for collation. Here is a reminder of the URL: <http://www.bnms.org.uk/general/adverse-reactionsproduct-defects.html>

Investigational Medicinal Products and the Clinical Trials Authorisation (CTA) process

James Ritchie and Nigel Westwood from the Cancer Research-UK (CR-UK) Drug Development Office attended the April meeting of the UKRG and gave a stimulating presentation on the CTA process. From this it was agreed that a one-day joint CR-UK/UKRG workshop should be held to share successful approaches and identify best practice; this has been arranged for **23rd October 2012** in London. Newsletter readers interested in the challenges and demands of manufacturing radiopharmaceutical IMPs for early phase clinical trials are encouraged to book this date in their diaries. Further details will be available in the next Newsletter, after the June UKRG meeting.

SNOMED Clinical Terms (CT) and the coding of Radiopharmaceuticals

The UKRG working group has submitted some comments on the draft proposals to the project team at Connecting for Health (CfH). Emma Melhuish from CfH will attend a meeting with the working group and other members of UKRG on 27th June 2012 to discuss progress with the project. There will be an update in the next Newsletter.

UKRG advice on the safe drawing up of radiopharmaceuticals

This new guidance document, entitled "Safe drawing up of radiopharmaceuticals in nuclear medicine departments", is intended to provide guidance to Nuclear Medicine Departments on the provision and design of clinical facilities, procedures, documentation, training and audit in order to minimise the risks that arise from drawing up patient doses of radiopharmaceuticals in areas other than controlled pharmaceutical environments. It has been prepared by the UKRG on behalf of the BNMS, and is available on the UKRG website at this URL:

http://www.bnms.org.uk/images/stories/UKRG/UKRG_Drawing_up_Feb-12.pdf

NHS "SPECIALS"

National Database of NHS "Specials"

Readers are reminded that Version 2 of the National Database of NHS "Specials" is operating at this URL: www.pro-file.nhs.uk Registration is required to use the site but once logged-in much useful information is available to you.

Withdrawal of Products / Supply Issues

IBA PulmoCIS

Mike Ward of IBA has advised that PulmoCIS is expected to be available again from 18th June 2012.

Covidien "cold kits"

The problems with MAG3 have been resolved and stock is now available again. There continue to be some ongoing production problems with HDP, DTPA and PYP which are only available in limited quantities.

Draximage Medronate (MDP)

Guerbet had said that they will continue to be able to supply Draximage HDP until the end of June after which their distribution arrangements with Jubilant cease. It is not clear yet which company, if

any, will be the UK distributor from July onwards although UKRG understands that negotiations are in the final stages for appointment of a new UK distributor.

MOLYBDENUM

Molybdenum supplies

At the time of writing there seems to be some stability now in Mo99 supplies after a short "hiccough" in late April / early May. UKRG will continue to report any anticipated supply problems as information becomes available.

INDUSTRY NEWS

Ge68/Ga68 Generators

Imaging Equipment Ltd has announced that Eckert and Ziegler Radiopharma GmbH has obtained a local State Certificate of GMP Compliance for their new Ge68/Ga68 generator manufacturing plant in Berlin, allowing the generators to be used for clinical studies. This is an exciting first step in making these generators more widely available, including in the UK; the next step is for E&Z to apply the German National Authorities for formal Marketing Authorisation (MA).

Dry-block boilers

Validation of dry-block boilers for radiopharmaceutical preparation

For many years radiopharmacies have used some form of water bath for the preparation of radiopharmaceuticals in which radiolabelling only occurs at elevated temperatures, most commonly at 100°C. Covidien have recently been supplying users with dry-block boilers for the preparation of MAG3 and SestaMIBI. At least one member of the UKRG Committee, having used a dry-block boiler for MAG3, obtained only a 42% labelling efficiency. The MHRA Inspector at the meeting expressed the opinion that, if the SPC requires the product to be boiled and a dry-block boiler is used, the validation of such use is required otherwise the product will be considered to have been prepared "off-licence".

REGULATORY ISSUES

Re-sheathing of needles

There is nothing new to report on this topic at present, other than that the national aseptics group (PASG) and QA Committee both share the UKRG concerns. An approach has been made to Catherine Duggan at the RPS to see what support the Society can give.

Recent MHRA inspections

During 2012-Q1 only one radiopharmacy had received a GMP Inspection; there was one "Major" relating to the site's Quality Management System with the following defects observed:

Release procedure – this was ill-defined and applied, with products being shipped before release.

Training – there was no three-monthly review of training.

Microbiological reports – these were not always available.

Complaints – there were delays in signing off complaints.

Delegation of sign-off – this was poorly controlled.

MEETING REPORTS

BNMS Spring Meeting 2012

I am grateful to Paul Maltby for providing this report.

The BNMS returned to Harrogate this year for its 40th Annual meeting. Whilst the venue was the same – Harrogate International Conference Centre - lessons had been learnt from the last time we were there and the exhibition had been moved much closer to the main lecture, which made it easier for delegates to get to look around in the short times between sessions. For the first time as far as I am aware hot/cold food was laid on free at lunch times for all delegates to encourage folks to visit the exhibition. This was very welcome! Attendance was slightly down on previous years but the sessions were well balanced between proffered papers and invited reviews. For those who have never been to the Boot Camp on the Sunday afternoon preceding the main meeting I would recommend this as it provides excellent in depth

reviews over a continually changing theme of topics.

Unfortunately the invited speaker for the BNMS Annual Lecture had to cancel at short notice, so Prof Alan Perkins and Prof Ralph McCready stepped into the breach and presented a fascinating and entertaining history of radioactivity and nuclear medicine in the UK. In addition the presentation dinner had a "40-year" theme with several of the guests dressed in red, or as gangsters from the 40's which made an nice final touch to a very enjoyable meeting. Specifically the first joint session between radiopharmaceutical sciences and the clinical practitioners was successful and helpful presentations from the HSE has gone some way to resolving our issues around radiation doses to the lens of the eye and to the re-sheathing of needles. Many of the reviews (including the HSE presentations) are now available on the BNMS website (*Editor's note – to BNMS members only*).

TSET Competency Framework

The Pharmacy Technical Specialist Education and Training (TSET) Group is drafting a "Resource Document" and has sought ideas from UKRG for topics to be included to ensure radiopharmacy is covered adequately. If any Newsletter reader has any views on what should be included in this important resource please contact the Editor, or Bev Ellis direct at bev.ellis@manchester.ac.uk

Postgraduate Course in Radiopharmacy

Many thanks to Jim Ballinger (GSTT) for this information about a useful CPD opportunity.

The Postgraduate Course in Radiopharmacy will be held **Tuesday 11 December to Friday 14 December** at St Thomas' Hospital, London. The content has been organised so that each day (more or less) has a single theme: background/review, radiopharmaceutical chemistry, regulatory issues, and clinical radiopharmacy. Online registration is encouraged and electronic payments can be accepted.

https://www.kcl.ac.uk/prospectus/shortcourses/index/name/postgraduate-course-in-radiopharmacy-2012/alpha//month//day//header_search/radiopharmacy

If the link doesn't work, please go to www.kcl.ac.uk, select Study, then Short Courses, then search on Radiopharmacy.

Thanks to the UKRG members who participate in this course and who have sponsored attendance by their members of staff.

UPCOMING MEETINGS

2012

Society of Nuclear Medicine (SNM) 59th Annual Meeting

9–13 June, Miami Beach, Florida, USA

www.snm.org/am12

WMIC 2012: World Molecular Imaging Congress

5-9 September, Dublin, Ireland

www.wmicmeeting.org

11th International Isotope Symposium on the Synthesis and Applications of Isotopes and Isotopically Labelled Compounds

9-13 September, Rupprecht-Karls-Universität,

Heidelberg, Germany, www.iis2012.unitt.de/iis2012/

Medical Physics & Engineering Conference (MPEC) 2012

10–12 September, University of Oxford

www.ipem.ac.uk

British Nuclear Medicine Society (BNMS) 2012 Autumn Meeting

13-14 September, University of Oxford

www.bnms.org.uk

7th International Symposium on Radiohalogens

15-19 September, Whistler, British Columbia, Canada

<http://7isr.triumf.ca>

European Association of Nuclear Medicine (EANM) Annual Congress

27–31 October, Milan, Italy

www.eanm.org

ICRT 2012 – 7th International Conference on Radiopharmaceutical Therapy

25-29 November, Levi, Finland

www.eanm.org

2013

UKRG Annual Workshop

11 January, The Beeches Conference Centre Bournville, Birmingham, UK

Radiopharmacy Course

4-15 February, IEO - European Institute of Oncology, Milan, Italy
www.eanm.org

British Nuclear Medicine Society (BNMS) 41st Annual Meeting

22-24 April, Brighton, UK
www.bnms.org.uk

EANM'13 Annual Congress of the European Association of Nuclear Medicine

19-23 October, Lyon, France
www.eanm.org

2014

11th Congress World Federation of Nuclear Medicine and Biology (WFNMB)

27-31 Aug, Mexico
www.wfnmb.org

From the Editor

The next meeting of the UKRG Committee will take place at Aston University on 27th-28th June 2012. If readers have any issues they wish to be discussed please raise them with your regional rep on the Committee. Alternatively, comments on the Newsletter content or on any radiopharmacy issue can be sent direct to the Editor at the address below.

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