

## DART Newsletter June 2007



### Welcome to the first DART Newsletter!

This is the first issue of the DART newsletter which we will use to keep you informed about topics of interest to the Medical Devices sector.

We plan to provide regular updates and feedback to sponsors so to kick it off we thought that an introduction to the Medical Devices Staff – including the Devices Assistance for Regulatory Transition (DART) Team would be a good place to start.

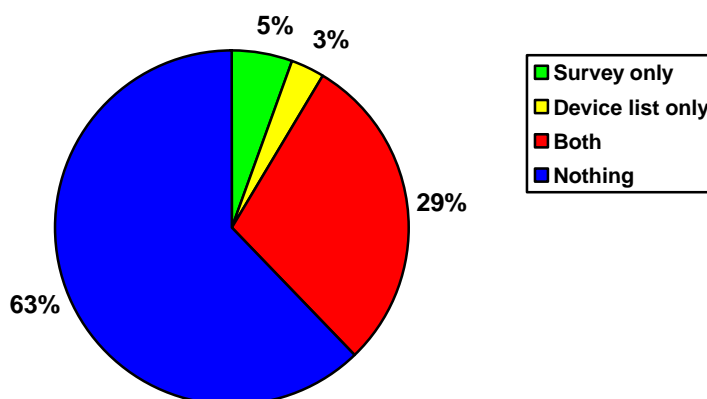
We also want to ensure that you have the 29 June pencilled into your diary for a morning or afternoon workshop based on refreshing your knowledge of WAND and providing assistance on some of the more technical aspects of device regulation such as GMDNs. You should have all received a notice about the workshop by now either by email or post, if not, please feel free to contact us on 0800 DEVICE or [DART@moh.govt.nz](mailto:DART@moh.govt.nz) and we can supply details to you. The close off date for confirmation of attendance is close of business on 22 June.

There has been a somewhat disappointing response to the WAND project from the letter that was sent out to all sponsors in March. Each letter was accompanied by a survey and a list of the sponsors WAND entries. We urge sponsors to take the opportunity to participate in this project as it will be of benefit to you through removal of obsolete entries, possible grouping of applications and the saving in fees relating to application audits if your notifications are assessed prior to ANZTPA going live.

There are 420 sponsors with medical devices notified on the WAND database. To date 160 WAND project surveys (or 38%) have been returned complete with a further 8 surveys returned undelivered.

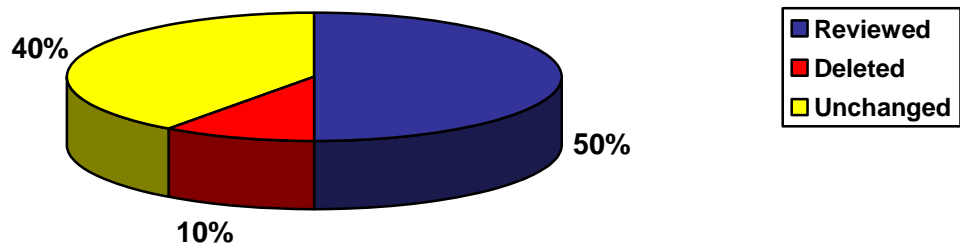
### Representative Graphs of Project Responses as at 8 June

#### Returned Documents



Of the device lists, 151 lists (36%) have been returned and have resulted in 1543 device notifications being made obsolete at the request of the sponsor.

## Phase One Deletions



### Device Team member Bios

The Medical Devices team at Medsafe has nine members, eight of whom are entirely or principally within the DART team in order to facilitate transition to the new regulatory framework.

The DART team members have been focusing on training to date but are now at a point where they are available to help you as and when you require it.

We have composed a short introduction to each member of the Medical Devices Team to give you a glimpse into the background of the people you will be dealing with.

#### Dr Sergey Bibikov

Sergey trained in medicine in Russia and has more than 15 years medical experience including as an Obstetrician and Gynaecologist, and as a breast cancer specialist. He ran a district oncology department for 5 years and a wholesale medical device and medicines business for 5 years. Since moving to New Zealand in 2003, Sergey has completed an MBA and an internship with PHARMAC.

#### Kimberly Bridgewater

Kimberly has a degree in Medical Technology/Clinical Laboratory Sciences from Louisiana State University. At Charity Hospital, New Orleans, she completed her training as a Generalist in all areas of laboratory science. Since her arrival in NZ in 2003, Kimberly has worked with Medlab in Queenstown, and in the Biochemistry departments at North Shore and Waitakere Hospitals in Auckland.

#### Rhondda Luton

Rhondda is a senior Registered Nurse who has worked in various areas of clinical practice including specialised unit work. She also holds a degree in education.

#### Jasmine Plimmer

Jasmine is a Registered Nurse with extensive experience in clinical nursing. She has specialised in cardiac and renal nursing, spending 7 years as the Charge Nurse of the Renal Ward at Wellington Hospital. Following this, Jasmine was an After Hours Manager for Hutt Valley Health DHB. Her most recent experience has been in the community as a Practice Nurse.

#### Ashleen Singh

Ashleen has a Biomedical Science degree majoring in human genetics and molecular pathology. She has worked in a hospital based sterile services department and as a cardiac technologist. Ashleen has also worked as a PA for a Wellington based Cardiologist and is continuing with post-graduate studies in medical technology.

### Jo Williams

Jo is a Registered Nurse with 11 years experience working in Wellington hospitals specialising in gastroenterology. Most recently she has worked for 18 months in occupational health as the company nurse for Mobil Oil NZ.

### Ruth Grant (Senior Advisor)

Ruth is a qualified Electronic Engineer specialising in biomedical engineering. She has extensive experience working with a broad range of medical devices, laboratory equipment, weighing devices and scientific instruments as well as experience conducting technical training and as a Service Development Manager. Ruth is also involved in Medical Device Standards development, Risk Assessment and Risk Management.

### Ian Ross (Senior Advisor)

Ian is a medical physicist with 37 years of clinical experience including direct patient diagnosis and treatment, specialising in clinical imaging. He is a founding member of several professional associations including the Australasian College of Physical Scientists & Engineers in Medicine and is also a national adviser in radiation safety. Ian established and ran the Wellington regional biomedical engineering service and established & headed a technology assessment group for Capital & Coast DHB. He is a long-serving member of various Standards Committees, and holds an MBA in technology management.

*Sergey, Kimberly, Rhondda, Jasmine, Ashleen, Jo, Ruth and Ian are all part of the newly formed Device Assistance for Regulatory Transition (DART) Team.*

*In addition to his role in the DART team Ian holds the responsibility at Medsafe for dealing with queries relating to the pre-market aspects of current regulatory requirements for medical devices*

### Robert Jelas (Senior Advisor)

Rob comes from an industry background where he has 14 years experience in sales and management of the importation and supply of medical devices, mostly for gastroenterology and interventional cardiac specialties. He has worked in both Australia and New Zealand.

*Rob has primary responsibility at Medsafe for medical device post-market surveillance including adverse event reporting, recalls and corrective actions.*

### **Feedback**

Any feedback that you wish to supply to us about this newsletter can be directed to [DART@moh.govt.nz](mailto:DART@moh.govt.nz). Your opinions and suggestions are valuable to us to determine the most useful information to provide to our medical device sponsors.