

MET News – November 2011

Team up with MET - Excellence in Medical Devices

Chemical Analysis

Do you make full use of chemical analysis in your medical device and manufacture?



Using our materials testing services can reduce costs significantly. In manufacture periodic verification of incoming materials and outgoing production can help prevent costly product recalls. When processes or manufacturing locations change, materials characterisation is the ideal method to validate the safety of any changes without resorting to toxicity testing.

In product development materials analysis can be used to reduce the biocompatibility testing burden. Both the FDA and the MHRA issue guidance which encourages chemical testing in place of toxicological testing.

FDA Guidance May 1, 1995 **Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'** *'Some devices are made of materials that have been well characterized chemically and physically in the published literature and have a long history of safe use. For the purposes of demonstrating the substantial equivalence of such devices to other marketed products, it may not be necessary to conduct all the tests suggested in the FDA matrix of this guidance.'*

MHRA Guidance 5 EC MEDICAL DEVICES DIRECTIVES **GUIDANCE ON THE BIOLOGICAL SAFETY ASSESSMENT** Updated February 2011 Tells us that biocompatibility testing is used to complement materials assessments. Also, biological testing may not be required for well characterised materials.

Talk to Our Experts

Consultancy services from MET now encompass: quality systems implementation, audit practice, 510k and technical file compilation. Our engineers have worked on many devices over a great many years giving us expertise in risk analysis and project implementation. Particular areas of strength are: biocompatibility testing, functional testing, packaging validation, stability studies and much more.



Also, don't forget that you can contact us through the chat area on our web site.

Call 08454 588924 or E-mail solutions@met.uk.com for impartial advice and free quotations.

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Thought provoking snippets from MET – November 2011

The Wrong Road

War is Hell we have been told
By those who ought to know
Yet when we're told "Go to it"
Like witless sheep we go

Father to the war camps
That stretch from pole to pole
Glad to be a-doing after years upon the dole

Mother to the factories
To learn to make a shell
And help some other mother's son
Along the road to Hell

Sonny out in theatre
Not to watch a show
Protecting our poor allies
From the all destroying foe

Daughter in the ATS
Behind a steering wheel
And when she's fairly started
Can make the road hogs squeal

They are reaching out for freedom
Their leaders tell them so
But who can gather Violets
Where only Thistles grow

What an idiot world it is
That we are living in
Like a puppy getting madder
With its head stuck in a tin

(Raymond Morris circa 1940)