

JACIE Newsletter



July 2010

Issue 3

Welcome

JACIE updated the web site earlier this summer. The redesign was kindly supported by an unrestricted educational grant from CHUGAI sanofi-aventis. We are still working on adding functionality but we believe that it is already a major improvement. The site contains a wealth of information relevant to centres, inspectors and anyone with an interest in JACIE.

If you have any suggestions for content to add to the site, please go to the feedback form [here](#). We would love to hear from you!

Wishing you a wonderful summer!

Catherine Foggo
On behalf of the JACIE Office Staff

Standards

5th edition overview

The Standards Development Steering Committee initiated the development of the 5th edition of the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration* this June in Barcelona, Spain. The purpose of this meeting, led by Carolyn Taylor, PhD, Standards Chair, was to review comments and survey responses submitted by cellular therapy programmes, establish overall goals for the new edition, and coordinate subcommittee activities.

The draft of the 5th edition will be available for public comment in mid-2011, with the final version being published in March 2012. Details and updates regarding the Standards development process will be provided as they become available.

News

Overview

Since 2000, JACIE has received 214 applications from centres in 17 countries. This is testimony to the global appeal and relevance of the FACT-JACIE standards.

Preparation for Inspection

Centres preparing for an on-site inspection must submit what can be a substantial quantity of documentation in advance. The list of documents is available in the Inspection Guide version 4.6 from the [Document Centre](#) on the JACIE web site.

Most centres submit carefully organised and presented collections of documents which greatly facilitates the task of the inspectors when they come to review the files before the inspection. Occasionally however submissions are less clearly organised or files have titles that make it difficult to know what they refer to. This can make the inspectors' task more difficult and time-consuming.

In order to help centres and standardise the way documents are submitted, the JACIE Office has released a new tool based on a zip file that contains a pre-formatted series of folders and sub-folders for each section of the standards that the centre can use to group and classify their files. The zip file and instructions are available from the [Document Centre](#) on the JACIE web site.

Accreditation Statistics

Total centres registered:
214

Inspections in preparation:
First time: **55**
Reaccreditation: **17**

Total completed inspections:
First time: **152**
Reaccreditation: **33**

Accreditations: **97**

Facilities correcting deficiencies: **23**

Number of countries registered: **17**

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Surveys

FACT-JACIE Standards Survey

FACT and JACIE invite you to complete a short survey focusing on general concepts of interest. You are also encouraged to promote this survey in your national or regional professional society.

The results of this survey will be reported to the Standards Steering Committee for review and consideration.

Access the survey at <https://www.surveymonkey.com/s/HMRS6ZH>.

Up and coming JACIE Surveys

JACIE will shortly be circulating surveys to the JACIE Inspectors as well as to centres. The aims of these surveys will be to assess their needs, provide updates, and identify and develop ongoing services. We would really appreciate your valuable feedback as soon as the surveys are released in the next few weeks.

Quality Management

3rd EBMT Quality Management Meeting, EBMT 2011

The Quality Management Group have recently met and have now proposed the preliminary programme for the 2011 EBMT Annual congress which will be held in Paris, France. The proposed programme is awaiting feedback and approval from the 2011 Congress Scientific Committee. Once the programme has been approved and finalized, it will be announced on the JACIE website and Newsletter. What we can confirm at this stage is that you won't want to miss out!

The Quality Management Group would like to thank everyone for all of their helpful and valuable comments, suggestions and feedback.

Important dates for your diary

Congresses and Annual Meetings

11-14 Sep 2010 - Belgirate, Italy ISCT Annual Meeting www.isct-europe.eu/2010/

3-6 Apr 2011 - EBMT 2011 Annual Congress, Paris, France www.congrex.ch/ebmt2011/

Training Courses and Events

10-11 Sep 2010 - Belgirate, Italy - Inspector Training Course ****no availability****

18-19 Nov 2010 - Barcelona, Spain - Internal Audit Training Course ****don't miss out****

Feature Course - Internal Audit Training Course

Audits are key elements of any quality management system, but JACIE inspections have shown that this is an area that transplant programmes struggle with. This course will include preparing for and performing internal audits and how to evaluate and act upon the results. Participants who attend this course will gain the necessary skills to successfully complete internal audits.

If you are interested in attending a JACIE Training course and wish to register or would like further information, or if you would like us to consider promoting an upcoming event here, please do not hesitate to contact us jacie@ebmt.org

JACIE Office

At the end of July, Eoin James Mac Hale will leave JACIE to take up a position with an international consultancy firm. Eoin joined JACIE in 2006 and during those four years he left his mark on the organisation through his professionalism, thoroughness and energy. He demonstrated a keenness to gain new understanding and knowledge in what is a continuously changing sector. Committed to excellent customer service, it is safe to say that he has always left a positive impression on anyone who had contact with him whether by email, telephone or in person and he will be greatly missed. JACIE would like to thank him for all his contributions and to wish Eoin every success in his new position.

TOP TIPS

In this issue our TOP TIPS are for those -

After the onsite Inspection

Make notes during the Exit Interview.

This way you can start working on your corrections straight away!

Communicate the feedback to the wider team – not everyone attended the exit interview

Have a party to celebrate this great achievement! But bear in mind that it is not all over yet – there will be corrections that will need to be made

All programmes have corrections!

Complete the onsite evaluation survey and return it to the JACIE Office – your feedback is essential



Eoin James Mac Hale