



JACIE Newsletter



December 2010

Issue 4

Welcome

To the final newsletter of 2010. This edition brings you important training and event information for 2011, including sessions at the 2011 EBMT Annual Congress, Paris, France that you won't want to miss out on – so mark the dates in your diary!

We hope that you have enjoyed the newsletters this year. They will continue in 2011, keeping you up to date with the latest JACIE news and information.

The JACIE Office would like to take this opportunity to wish you all the best during this festive season and throughout 2011.

Catherine Foggo
On behalf of the JACIE Office Staff

5th edition FACT-JACIE Standards

The work on preparing the 5th edition of the Standards commenced in June 2010 with a kick-off meeting by FACT and JACIE representatives in Barcelona. The meeting established the bases for preparing the next edition and for the work being done by the respective Standards Sub-Committees who have been meeting by teleconference since September.

This phase will finish towards the end of 2010 or the beginning of 2011. Another FACT-JACIE meeting will then take place in mid-February at the BMT Tandem Meeting in Hawaii to finalise the first draft of the Standards.

The following step will be to make the draft text available for public consultation in Spring 2011 (dates to be confirmed). This consultation will be announced on the JACIE web site and newsletter. You are encouraged to review the draft when it is released and return your comments for consideration by the Standards Committee.

Publication of the 5th edition is set for 1 March 2012.

News

Overview

Since 2000, JACIE has received 224 applications from centres in 17 countries. In the same period, almost 200 inspections have been performed.

Italian JACIE Information Course

The European Institute of Oncology, Milan, Italy, organized a JACIE course "L'accREDITamento Jacie: soluzioni e consigli per migliorare l'iter realizzativo" in November to meet the huge interest of different Italian transplant centres who are applying now for JACIE accreditation.

With the participation of dott. Rambaldi, dott. Introna and dott.ssa Lombardini, the discussion analysed some key points of the JACIE Accreditation process (indicators and outcome analysis, quality control and interaction between facilities, education and competency maintenance of medical and nurses staff, technical tools etc). The course saw the active participation of over 120 professionals (physicians, nurses, biologists, data managers and technicians) from all over Italy.

Due to its success, the European Institute of Oncology, Milan, Italy, have been requested to repeat this Course in October 2011 as a 2 day course.

Accreditation Statistics

Total centres
registered:
224

Inspections in
preparation:
First time: **54**
Reaccreditation: **21**

Total completed
inspections:
First time: **162**
Reaccreditation: **36**

Accreditations: **104**

Facilities correcting
deficiencies: **25**

Number of countries
registered: **17**

CONTACT US

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Quality Management

3rd EBMT Quality Management Meeting, EBMT 2011

The Quality Management Group is very satisfied that their proposal to change the format of the meeting was approved by the congress Scientific Committee. The result is that sessions will be distributed across Monday and Tuesday rather than being isolated at the end of the congress. The Group is convinced that the topics and layout will make for a very interesting meeting. All of the information concerning the programme and registration can be found at <http://www.congrex.ch/ebmt2011/> and an overview can be found on page 4 of this newsletter.

Important dates for your diary

Congresses and Annual Meetings

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

18-21 May 2011 Annual ISCT Meeting, Rotterdam, The Netherlands
www.celltherapysociety.org

Training Courses and Events

3 Apr 2011 - JACIE Inspector Workshop (registered JACIE Inspectors only), Paris, France

16-17 May 2011 - JACIE Inspector Training Course, Rotterdam, The Netherlands

18 May 2011 - FACT-JACIE Workshop, ISCT Annual Congress, Rotterdam, The Netherlands

20-21 Jun - JACIE · Kertezza Internal Audit Training Course, Barcelona, Spain

13-14 Sep 2011 - JACIE Centre Preparation Course, Barcelona, Spain

15-16 Sep 2011 - JACIE Inspector Training Course, Barcelona Spain

14-15 Nov 2011 - JACIE · Kertezza Internal Audit Training Course, Barcelona, Spain

For more details, please refer to pages 3 and 4 of this newsletter.

All courses have limited availability. Full programme details as well as the registration costs and process will be announced shortly.

JACIE Board changes

There have been important changes to the Board of JACIE. On 1 October, 2010, Jane Apperley (London, UK) ended her term as President of JACIE. Christian Chabannon (Marseille, France), following his two years as Vice-President, has now taken on the Presidency for the next two years. The new Vice-President is Alessandro Rambaldi (Bergamo, Italy) following his designation by the EBMT Board. Jane will continue to contribute to the Board for a further 12 months as Past-President and sincere thanks are due for her leadership of JACIE over the past two years.

JACIE Office – new staff

Iris Bargalló (Barcelona, Spain) has joined the JACIE Office as the new Accreditations Coordinator. Iris previously worked in the multinational company Würth where she was responsible for achieving and maintaining authorisation for importation and distribution of medical devices. She also coordinated quality control of products and built key relationships with the company's marketing and distribution departments.

Iris is keen to develop her knowledge of quality in healthcare and is excited by the opportunity to work with JACIE.

Iris holds a degree in Chemistry from the University of Barcelona and spent two years working and studying in Newcastle, United Kingdom.

She will be at the EBMT Congress in Paris next April.

Barbara Bellina (Lima, Peru) started working with JACIE at the end of September as Administration Assistant. Barbara is a full-time student of Business Administration in the University of Barcelona and is working part-time in the JACIE Office providing administrative support to the team.



Iris Bargalló
Accreditations Coordinator



Barbara Bellina
Administration Assistant



Christian Chabannon
President JACIE



Alessandro Rambaldi
Vice-President JACIE

TOP TIPS

In this issue our TOP TIPS are for those -

Corrective Actions after the onsite Inspection

Read the Summary Report when you receive it from the JACIE office

Confirm to the JACIE Office that you have received the Summary Report and that you agree with the findings. If you do not agree, contact the JACIE Office

Create a work plan for the corrective actions, ensuring that you have a realistic timeframe

Make sure those that are involved are informed about what changes need to be made and the timeline

When submitting the corrective actions to the JACIE office, ensure that the exact document name is written in the relevant section in the Summary Report. This makes it easier for the JACIE Office and the Inspector to identify the correct document

Double check that you have all of the documentation that supports your corrective actions before submitting them to the JACIE Office



Training Courses and Events for 2011

14-15 March <i>To be confirmed</i>	JACIE Centre Preparation for Paediatric Centres in collaboration with the EBMT PDWP	Barcelona, Spain
3 April	JACIE Inspector Workshop, EBMT Annual Congress (Registered JACIE Inspectors only)	Paris, France
3-6 April	2011 EBMT Annual Congress	Paris, France
16-17 May	JACIE Inspector Training	Rotterdam, The Netherlands
18 May	FACT JACIE Workshop, ISCT Annual Meeting	Rotterdam, The Netherlands
20-21 June	JACIE · Kerteza Internal Audits	Barcelona, Spain
13-14 September	JACIE Centre Preparation	Barcelona, Spain
15-16 September	JACIE Inspector Training	Barcelona, Spain
14-15 November	JACIE · Kerteza Internal Audits	Barcelona, Spain

Centre Preparation Training Course

The course covers the implementation of a quality management system, including topics such as document control and project management. This course is aimed at anyone involved in or preparing for JACIE Accreditation.

Inspector Training Course

JACIE requires that all Inspectors attend a JACIE-approved training course in order to ensure uniformity and consistency in interpretation of the Standards and performance of the inspection. The course includes assessing a quality management system, interpretation of the standards and how to prepare and perform an inspection. The inspection is an excellent learning mechanism, both for the centre and the inspector as you will have a unique opportunity to see how other centres solve problems and observe their procedures up close and to transfer your own experience.

JACIE · Kerteza 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.

FACT · JACIE Workshop

We are delighted to announce the first joint workshop between FACT and JACIE. There will be morning parallel sessions and a joint afternoon session. JACIE's morning session will focus on the Inspection process for inspectors and Applicants, giving an introduction to the JACIE inspection process – the “what” and “how” of a quality system and quality documents. After lunch both groups will join together for sessions including an updates on the Standards, gathering evidence and common citations.

All courses have limited availability. Full programme details as well as the registration costs and process will be announced shortly.



2011 EBMT ANNUAL CONGRESS, PARIS, FRANCE

Important sessions for your diary

Sunday 3 April 2011

JACIE Inspector Workshop

14:00-17:00 JACIE would like to invite registered JACIE Inspectors to attend the JACIE Inspector workshop to advanced their auditing skills, at the 2011 EBMT Annual Congress, Paris, France ***DON'T MISS OUT***

Monday, 4 April 2011

Quality Management Workshops

10:00 – 11:00 Tools and Processes for Quality Improvement, Nick Fahie-Wilson (Tonbridge, UK)

10:00 – 11:00 How can adverse events and near misses lead to organisational change? R. Amalberti (Haute Autorité de Santé, FR)

JACIE Session

12:00-13:00 There will be three topics covering

- Developments in the 5th edition of the FACT-JACIE Standards
- The annual European Union survey of adverse events
- A presentation of the European Federation of Immunogenetics (EFI) accreditation scheme for HLA typing laboratories and their incentives programme.

Quality Management Lecture

13:00 – 14:00 An audit system: theory & practice P. Corstiaans (Kasterlee, BE)

Quality Management Workshops (repeated from the morning session)

15:00 – 16:00 Tools and Processes for Quality Improvement, Nick Fahie-Wilson (Tonbridge, UK)

15:00 – 16:00 How can adverse events and near misses lead to organisational change? R. Amalberti (Haute Autorité de Santé, FR)

Quality Managers' Reception

16:30 – 18:00 For people working in quality management wishing to share experiences and to avail of an opportunity to meet colleagues also working in this increasingly important area.

Tuesday, 5 April 2011

Quality Management Language Forums

10:00 – 11:00 English speaking language forum K. Patel (London, UK); A. Emmett (Newmarket, UK)

10:00 – 11:00 French speaking language forum P.E. Donot (Lyon, FR); P. Huynh (Brussels, BE)

All of the information concerning the programme and registration can be found at
<http://www.congrex.ch/ebmt2011/>