



# 3<sup>rd</sup> International EuBIS Seminar and Training

## Quality management and inspection criteria for blood establishments

7<sup>th</sup> – 9<sup>th</sup> of March 2012, Leuven, Belgium



*From 'good to best' practice*

organised by the EuBIS Academy  
in cooperation with the Rode Kruis-Vlaanderen Belgian Red Cross – Flanders

supported by the

**EBA** European  
Blood Alliance

  
**Rode Kruis**  
Vlaanderen



## 3<sup>rd</sup> International Seminar and Training Course – Leuven, 7<sup>th</sup>-9<sup>th</sup> of March 2012

### Invitation

Dear interested participants,

*the EuBIS Project, initiated under the Public Health Programme of the European Commission, Directorate General SANCO, has developed manuals containing standards and guidelines for quality management and the inspection of blood establishments. Based on the EuBIS manuals the EuBIS Academy has organised training seminars and courses in order to promote knowledge in the area of quality and safety of blood and blood components throughout Europe.*

*Following the 1<sup>st</sup> International seminar during the ISBT congress in Berlin, Germany and the 2<sup>nd</sup> International Seminar and Training Course organised in cooperation with the Centro Nazionale Sangue (CNS) in Rome, Italy, we have received pre-registrations from several institutions interested in participating training in quality management and regulatory inspections of blood establishments.*

*The 3<sup>rd</sup> EuBIS International Seminar and Training Course is organised by the EuBIS Academy in cooperation with the Belgian Red Cross-Flanders (Rode Kruis-Vlaanderen) and will be a further milestone in the objectives of EuBIS to give assistance in promoting its the mission 'from good to best practice'.*

*On behalf of all EuBIS Project participants, Collaborating partners and the Academy trainers, we would be happy to welcome all of you to Leuven, Belgium and hope that we will have an exciting training including fruitful discussions and extensive exchange of ideas.*

*Prof. Dr. Christian Seidl  
EuBIS Academy Coordinator*

*Jan Ceulemans  
EuBIS Academy Organiser*

*Prof. Dr. Philippe Vandekerckhove  
Director and CEO, Belgian Red Cross-Flanders*





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### EuBIS Academy Members – Training Sessions:

Jan Ceulemans, HBRC-RKV, Belgium  
Boudewijn Hinlopen, Sanquin, The Netherlands  
Dr. JP Jansen van Galen, Sanquin, The Netherlands  
Dr. Helga Huber, PEI, Germany  
Dr. Fewzi Teskrat, AFSAPPS, France  
Prof. Dr. Christian Seidl, BSD-BH, Germany

### Organisers:

Prof. Dr. Christian Seidl, EuBIS coordination office  
Prof. Dr. Dr. h.c. Erhard Seifried, BSD-BH  
Prof. Dr. Philippe Vandekerckhove, HBRC-RKV, Belgium  
Jan Ceulemans, HBRC-RKV, Belgium

### Affiliates:

Dr. Alex Aquilina, Coordinator - European Training in Transfusion Medicine, EBA

### Meeting Venue:

#### **Bloedtransfusiecentrum Vlaams-Brabant-Limburg**

Herestraat 49  
3000 Leuven  
Tel.: 078 05 01 11

### Course language

English

### Registration Fee:

The following registration fee applies: **470,- Euro**

**Joint Academy Dinner (Brussels) 55,- Euro**

For registration please refer to:

*EuBIS Coordination Office*

Mrs. Tanja Knoth

DRK-Blutspendedienst Baden-Württemberg-Hessen

Sandhofstrasse 1

60528 Frankfurt am Main

Tel.: +49-6782-444

Fax.: +49-6782-254

e-mail : [EuBIS@blutspende.de](mailto:EuBIS@blutspende.de)

Course Information : [www.eubis-europe.eu](http://www.eubis-europe.eu) (application forms)



## 3<sup>rd</sup> International Seminar and Training Course – Leuven, 7<sup>th</sup>-9<sup>th</sup> of March 2012

### Wednesday the 7<sup>th</sup> of March 2012

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- 9:00-12:00 Seminar I – Quality management and inspections  
EuBIS Manual and Training Guide**  
Introduction of the trainers and the participants 'Break the Ice'
- Common regulatory requirements and essential quality standards  
(EuBIS manual and guide)
- Quality management of blood establishments  
Standards and criteria of the EuBIS manuals and guide and its practical use  
related to Rode Kruis-Vlaanderen Services
- Discussion*
- 12:00-13:00 Lunch break (served in the meeting room)
- 13:00-18:00 Training Exercises**
- 13:15 Training exercises and group work – Introduction
- 13:30 -15:00 Exercise 1 - Inspection design and donor collection**  
1.1. Design an inspection  
1.2 Donor collection activities  
Discussion (Plenary Session)
- 15:30 -17:00 Exercise 2 - Donor eligibility, blood donation and blood processing**  
2.1 1st case study – Adverse event on blood processing  
Group Work and plenary session  
2.2 Quiz 1: Donor eligibility / Blood donation  
Individual Work and plenary session)
- 17:00-17:30 Summary and conclusion of learning points (Day 1)**  
Discussion (Plenary Session)
- 18:30 – 23:00 **Joint Dinner (Brussels)** for EuBIS course participants and Academy members  
Tour to Brussels Old City (free)



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### Thursday, the 8<sup>th</sup> of March 2012

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#### 9:30 - 10:30 Seminar II - Quality management and inspections EuBIS Manual and Training Guide – Practical Examples

Quality indicators for blood components for transfusion and reference to the EuBIS manual and guide

Risk assessment and management of errors in blood establishments based on the EuBIS manual and guide

Discussion (all participants)

#### 10:45 - 18:30 Training Exercises

##### 10:45-12:30 Exercise 3 – Blood collection, Storage and distribution, Quality management

Classification of non-compliances  
Group Work and plenary session

12:30 – 13.15 lunch

##### 13:15 - 14:30 Exercise 4 – Video Training of non-compliances Blood processing and blood collection

Individual work and plenary session

##### 14:45 - 16:30 Exercise 5 – Quality assurance and Inspection/Audit report

(Writing a comprehensive and clear non-compliances in an inspection/audit report)

- 5.1 Writing non-compliances / reports
- 5.2 Quiz on quality assurance

##### 16:45 - 17:30 Exercise 6.1 – Briefing of participants for the On-site-Inspection-Visit

Overview of On-Site Inspection facilities  
Site-master-File and audit trail (3 Inspection teams)

##### 17:30 - 18:00 Summary and conclusion of learning points (Day 2)

Discussion (Plenary Session)



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### Friday, the 9<sup>th</sup> of March 2012

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9:00 - 12:30 **Seminar III - Quality management and inspections**  
**EuBIS Inspection On-site Visit**

9:00-9:30 Set-up of Group A and Group B and Group C for On-site-Inspection-Visit

- Blood Processing
- Blood Collection
- Blood Testing

**9:30 - 11:15 Exercise 6.2. – Inspection (Visit) to the Leuven Blood Transfusion Center**  
Inspection Visit of the BE facilities  
concluded by Round Tour of blood establishment

11:30 – 12:45 **Exercise 6.3. - Report observations (Group A and Group B)**  
Group work and plenary discussion

12:45 – 13:30 Lunch

13:30 - 15:00 **Exercise 7 – Blood testing - role play (BE/CA)**  
Discussion (Plenary Session)

15:30 – 16:00 **Summary and conclusion of learning points (Day 3)**  
Training Course evaluation form

16:00 – 16:30 **Concluding remarks and *EuBIS Training Certificates***



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### Seminar and training scope:

Comprehensive overview of commonly used standards and criteria summarised in the EUBIS manual and training guide

Learn to define critical sub-processes for quality management

Advanced knowledge on how to use the cross-reference to commonly used standards and regulatory requirements such as the

- EU blood directive
- GMP standards
- CoE (EDQM) guide
- PIC/S guidelines.

Learn common practice and get practical advice for the inspections of blood establishments covering the

- collection,
- processing,
- testing
- storage and distribution

of blood and blood components.

Practical exercises to train your knowledge in

- Planning of inspections and defining critical control points
- Risk based assessment and management of errors
- Observation and communication skills
- Classification of observations and errors

Finally the training course will be an excellent opportunity to meet experts in the field coming from blood establishments and competent authorities.

**Language skills:** English



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#### Leuven \*

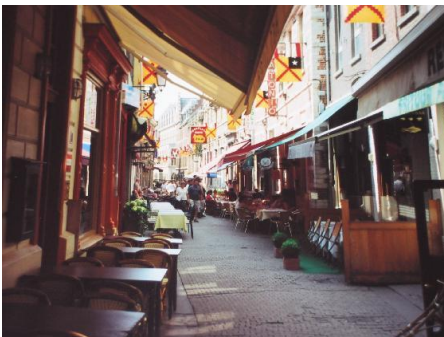
The earliest mention of Leuven ("Loven") is from 891 when a Viking army was defeated by the Frankish king Arnulf of Carinthia (see: Battle of Leuven). According to the city legend, its red-white-red colours depict the blood-stained shores of the river Dijle after this battle.

Situated at this river and nearby the stronghold of the Dukes of Brabant, Leuven became the most important centre of trade in the duchy between the 11th and the 14th century. A token of its former importance as a centre of cloth manufacture, is nicely reflected in the typical Leuven linen cloth, known in late 14-15th century texts as *lewyn* (other spellings: *Leuwyn*, *Levyne*, *Lewan(e)*, *Lovanium*, *Louvain*). In the 15th century a new golden era began with the founding of the by now largest and oldest university in the Low Countries, the Catholic University of Leuven, in 1425. In the 18th century Leuven became even more important as a result of the flourishing of the brewery now named AB InBev, and whose flagship beer, Stella Artois, is brewed in Leuven. Leuven is also the worldwide headquarters of Anheuser-Busch InBev, the largest beer company on the planet

Being the capital of the region of Flemish-Brabant means that there are many governmental institutions located in Leuven. Nowadays Leuven is a real "student city", as during the academic year most citizens in its centre are students. Leuven has one of the liveliest bar scenes in Belgium. Besides boasting the "longest bar" in Belgium, the Old Market, dozens of bars and cafés crammed into a central square in Leuven, it's also the proud home city of Belgium's smallest bar, Ouder den Toog in the Noormannenstraat



Leuven Town Hall and Oude Markt (Belgien)



Leuven: Muntstraat and Castle Arenberg



\* text and picture taken from wikipedia and/or wikitravel



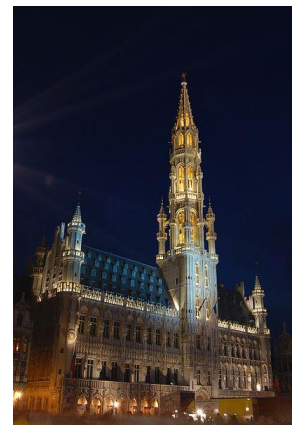


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### Brussels

Brussels (French: *Bruxelles*, Dutch: *Brussel*) is the capital city of Belgium and of Brussels Capital Region. It is entirely surrounded by Dutch-speaking Flanders and its constituent Flemish Brabant province. As headquarters of many European institutions and the European Commission, Brussels might also be considered something of a capital for the European Union.

The **Atomium** is a monument in Brussels, originally built for Expo '58, the 1958 Brussels World's Fair. Designed by André Waterkeyn, it stands 102 meters (335 ft) tall. The monument was originally planned to stand there for six months. However, it became a symbol not only of the World's Fair but also of modern architecture and the city of Brussels and of Belgium. It received monument status and stayed on the former exhibition grounds for over 50 years. It is now one of Brussels' main attractions.



Brussels: Atomium and Grand Place



Bloedtransfusiecentrum Vlaams-Brabant-Limburg in Leuven



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### **Social events**

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#### **City tour to Brussels Old City**

Wednesday, the 7<sup>th</sup> of March

free of charge

#### **Joint Dinner Academy and Training Participants in Brussels (optional) \***

Wednesday, the 7<sup>th</sup> of March

**55,- Euros (pre-registration required)**

#### **Collected Transfer (Mini-Bus) to Airport in Brussels**

Friday, the 9<sup>th</sup> of March

**appr. 30,- Euro / Person**

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***EuBIS***

***European Blood Inspection System***

*Initiated under the Public Health Programme of the EC – GA No. 2006202*

**3<sup>rd</sup> International Seminar and Training Course – Leuven, 7<sup>th</sup>-9<sup>th</sup> of March 2012**

## Meeting Venue

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### **Bloedtransfusiecentrum Vlaams-Brabant-Limburg**

Herestraat 49  
3000 Leuven  
Tel.: 078 05 01 11

#### Local Organiser:

Jan Ceulemans  
QA Manager  
Rode Kruis-Vlaanderen  
Dienst voor het Bloed  
p/a Bloedtransfusiecentrum Antwerpen  
B-2650 Edegem, Wilrijkstraat 8  
tel +32(0) 3 821 09 69  
GSM +32(0) 478 77 35 70  
email: [jan.ceulemans@rodekruis.be](mailto:jan.ceulemans@rodekruis.be)

#### Secretarial Office

Bernadette Ketele  
email: [Bernadette.Ketele@rodekruis.be](mailto:Bernadette.Ketele@rodekruis.be)



**EuBIS**

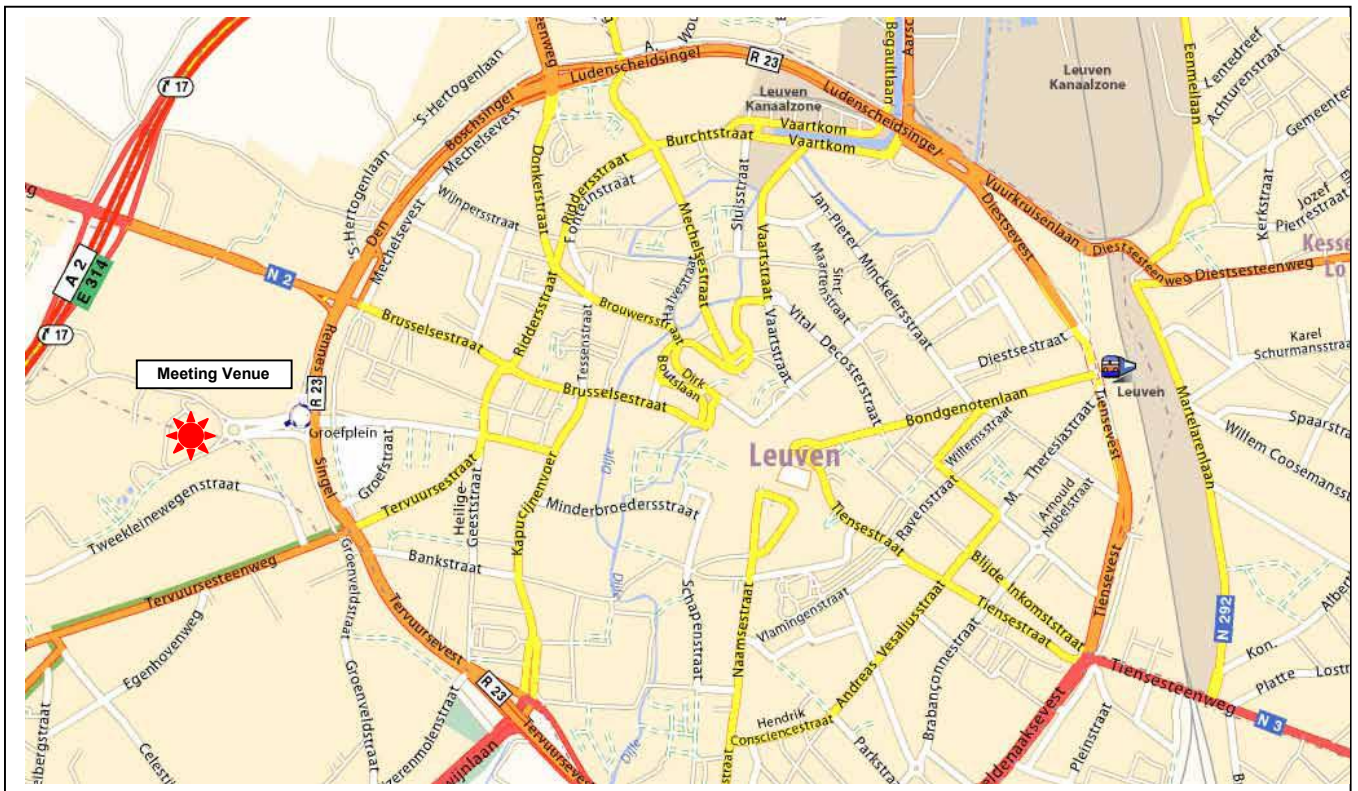
**European Blood Inspection System**

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Meeting Venue (MAP) - indicated by red Asterix \*

### Bloedtransfusiecentrum - Vlaams-Brabant - Limburg



#### Address

Herestraat 49/BTC  
3000 Leuven  
tel. 016 31 61 61  
fax 016 31 61 69  
vlaamsbrabant.limburg@rodekruis.be





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#### EuBIS Academy Members and Organisers

Name	Institution	Member State
Jan Ceulemans	QA Manager Rode Kruis-Vlaanderen Belgian Red Cross – Flanders, Antwerpen/ Edegem,	Belgium
Prof. Dr. Philippe Vandekerckhove	Director and CEO, Rode Kruis-Vlaanderen Belgian Red Cross – Flanders, Mechelen	Belgium
Dr. Fewzi Teskrat, MD	Conseiller Special Direction de l'inspection et des Etablissements Agence Française de Sécurité Sanitaire des Produits de Santé (AFSAPPS), Saint-Denis	France
Dr. Helga Marie Huber, PhD	Paul-Ehrlich Institute (PEI), Federal Ministry of Health Authority, Langen	Germany
Prof. Dr. Christian Seidl, MD	Vice Medical Director Red Cross Blood Donation Service – Institute of Transfusion Medicine and Immunohematology, Frankfurt/Main	Germany
Dr. Alex Aquilina, MD	Director National Blood Transfusion Service Malta, La Mangia	Malta
Boudewijn Hinloopen, Bed, BSc.	Head of Production Department Sanquin Blood Supply Foundation, Bloodbank North East Region, Groningen	The Netherlands
Dr. Jan Peter Jansen van Galen	Division Director Sanquin Blood Supply Foundation, Bloodbank North East Region, Groningen	The Netherlands

