EU-Q-Blood-SOP Project

Project Grant Agreement n^0 2004217

Interim Report 2006

Development of a pan-European standard operating procedure (SOP) methodology reflecting European best practice within the area addressing the quality and safety of blood

Co-funded by the European Commission – Directorate C 'Public Health and Risk Assessment'

Version 1.2 Frankfurt am Main, Germany, the 26th of October 2006. Co-funded by the European Commission. Directorate C 'Public Health and Risk Assessment'.

1 Introduction

The Grant agreement n0 2004217 ‘Development of a pan-European standard operating procedure (SOP) methodology reflecting European best practice (EU-Q-Blood-SOP) has been signed between the European Commission, Directorate General ‘Health & Consumer Protection, Directorate C – Public ‘Health and Risk Assessment’, SANCO C1/PAB and the main beneficiary on behalf of the associated beneficiaries in September 2005.

The project is co-funded by the European Commission, Directorate C – Public Health and Risk Assessment’, ‘Health & Consumer protection’ and will support the public health program on ‘quality and safety of blood’ in delivering a manual that will assist blood services to implement or expand their standard operating procedures (SOPs). The EU-SOP Manual will contribute to the understanding and management of quality processes in blood services and assist blood establishments in preparing for the inspection of their services related to the implementation of quality relevant elements required by the EU directive 2002/98/EC

The interim report is presented to the European Commission in order to summarize the results and deliverables obtained by the project thus far and to describe the current time table of the project.

Prof. Dr. med. Erhard Seifried (Project Leader)

Prof. Dr. med. Christian Seidl

PD Dr. med. Reinhard Henschler
Dr. Esther Schellenberg
Saman Hosseini

On behalf of the Project Participants and Nominated Persons

2 Project Methodology and Deliverables

The EU-Q-Blood-SOP Project involves blood establishments and governmental institutions in 16 EU member, acceding or EFTA states (see Annex I) and is overseen by an advisory board (Figure 1).

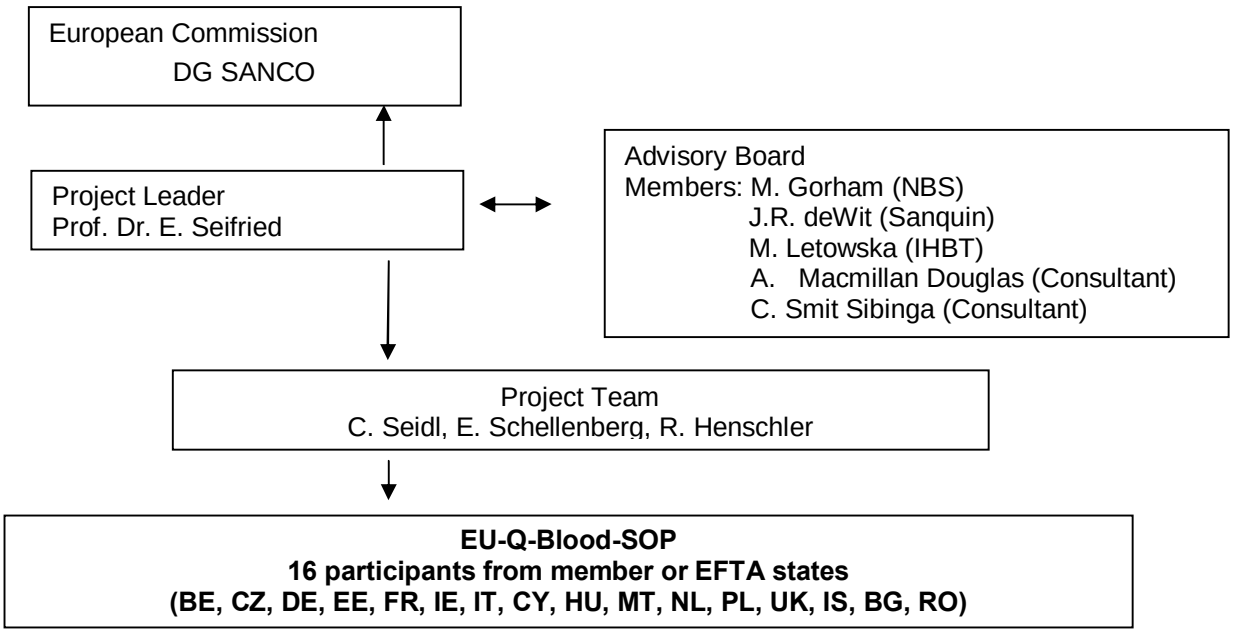

Figure 1: Structure of the EU-Q-Blood-SOP Project

The overall objective of the project is to contribute to good quality management (QM) in blood services, based on the requirements set out in Directive 2002/98/EC and its technical annexes. It will deliver this through the development of a manual that will assist blood services to implement or expand their standard operating procedures (SOPs). It is recognized that SOPs are only one aspect of QM.

The specific objectives are:

(1) assess the existence of SOP manuals and guidelines currently used in the 16 blood services involved in the project in order to identify (A) international and national SOP manuals already in place and (B) the current inspection practice;

(2) develop a manual to assist blood establishments to develop and implement their own SOPs.

(3) test this new SOP methodology among the partner institutions.

(4) produce this manual in 5 languages and distribute it to the participating blood establishments.

According to Annex I the following deliverables (D) have been defined:

Deliverable	Description
D1	**Questionnaire on current SOP structure** in 16 blood services of the participating members representing 17 EU member, acceding and EFTA member states.
D2	**EU-SOP survey report.** This report will be based on the compiled data of the returned filled-in questionnaires from the participants
D3	Creation of a **framework manual** by the project team.
D4	**SOP drafts** using the SOP methodology laid down in the framework manual.
D5	**EU-SOP Manual for blood establishments.** It will lay down the steps required for a blood establishment to create and write SOPs for its use.
D6	The **EU-SOP manual** will be delivered in **English** and **German** plus unofficially translated versions in, **French, Czech** and **Polish**.
D7	**Publication of the EU-SOP manual** in a paper back printed and .pdf electronic version.
D8	**Final project report**. The project team will prepare a final report on the project's outcomes and deliverables.
D9	**Publications and presentations** at meetings of professionals in the field of transfusion medicine.
	In addition the Project team proposed to establish an **Internet-based Project homepage** to be used to communicate the interim results and documents between the participants and to disseminate the Project's objectives and deliverables to the Public.

3. Description of work methodology and deliverables

3.1 Time Table

Project-Phase	Date	Work Process	Result / Deliverable
Start-Up	October 2005	**Communication 1 (C1)** sent to all participants including the announcement of the 1st Project meeting	Document (**C1**)
	October 2005	Advisory board meeting - Paris	completed
	October 2005	Installation of Project contact information: e-mail address and telephone Hotline	completed
Preparatory	October – November 2005	Design of Project Homepage together with Internet Company (Bernd Eder) including a public and membership area and a Web central structure	completed
	October – November 2005	**Design of Survey Questionnaire** Including final adaptation of content by members of the advisory board	Document **(D1) + (C2)**
	10. November 2005	Mailing of Survey Questionnaire to all participants. **Communication 3 (C3**)	Document (**C3**)
	14. November 2005	Mailing of financial budget information to all participants	completed
	November 2005	Final assignment of Nominated Persons by the project participants	completed
	6. December 2005	Homepage Information including member password sent to all participants **http://www.eu-q-blood-sop.de** **Communication 4 (C4)**	Document **(C4)** + Internet Link

	22-23 December 2005	Mailing of budget information to participants	completed
1st Meeting	November – December 2005	1st Project Meeting Registration and planning of Meeting by Project team. **Communication (C5**) Confirmation of Hotel reservation for participants, Conference Room Reservation including Catering	Document **(C5)**
	November – December 2005	Return of Questionnaires, Help-Desk (by e-mail and telephone) by the Project Management to all participants	completed
	December 2005 – January 2006	Evaluation of returned survey questionnaires by the project management team	Presentation **(PP1)** and **(PP2)**
	January 2005	The project team defines a list of minimum requirements for SOPs The list will contain - main principles of ISO/GMP/GLP - relevance of EU directive for inspections - definitions of quality relevant terms, giving a **SOP framework structure**	Presentation **(PP3)**
	19.-21. January 2006	**1st Project Meeting** in Frankfurt, DE	Meeting Program **(PP4)**
Manual Drafting	February - June 2006	Working Group drafting sample SOP	completed
	March 2006	**Project Survey Report** and Meeting Report	Document **(D2)**

	March 2006	Fine-tuning of SOP Master Documents and publication on the Project-Website (SOP Manual Draft)	Documents **(D3)** **+** **(D3-1-6)**
	March-April 2006	Working Group I Meetings organized by working group leaders and hosted by ISS (IT), HBTS (HU), IBTS (IE), NBS (UK)	completed
	May 2006	Publication of Working Group SOPs on Project Homepage Cross-linked between the working groups during the 2nd Joint working group meeting	Documents **(D4)** **D4-1** **D4-2** **D4-3** **D4-4-1** **D4-4-2**
	1.-3. June 2006	**2nd Joint Working Group Meeting** in Frankfurt, DE	Meeting Program **(PP5)**
	June 2006	Finalizing the master SOP structure and Publication on the public area of the homepage	Information on Internet **(D9)**
	12. July 2006	Advisory board Meeting – Helsinki	Completed **(PP6)**
	August 2006	Extending the Public Area of the Project Website giving information on the project deliverables	Information on Internet **(D9)**
	August-September 2006	Preparing the **Financial Interim Report**	Document **Annex III**
	September-November 2006	Manual Drafting Publication of the 'Framework Sample SOP' in the public section of the Internet **(D5)**	*In progress* **(D5-1)**

Test	September – January 2006	SOP test by working groups	*In progress*
	2. -7. September 2006	Presentation of Project results during the meeting of the International Society of Blood Transfusion (ISBT) in Cape town, SA	Publication **(D9)**
	19.-22. September 2006	Presentation of Project results during the joint meeting of the German Society for Blood Transfusion and Immunohematology and the International Society for cellular Therapy, Frankfurt, DE	Publication **(D9)**
	13.-14. October 2006	Presentation of Project results during the Meeting of the German Society of Immunogenetics, Innsbruck, AT	Publication **(D9)**
	12. October 2006	Advisory Board meeting in Ljubljana	completed
	November 2006	Article on project Results for professionals in the field to be published in 'Transfusion Today'	*In preparation*
	28.-29. November 2006	**Manual Drafting Team meeting** in Frankfurt, DE	*in preparation*
Manual Completion	February 2007	**2nd Project Meeting**	*In preparation*

3.2. Start-up phase

The project has been started in October 2005. At start, an informative **communication (C1)** has been generated and sent by e-mail to all participants. This communication has indicated to them that the project has started and has summarised the main activities and deliverables (see Annex IV). It included the information of the **project management team and the office** telephone and e-mail address. It has advised the participants that the 1st project meeting has been scheduled for the 19th – 21st of January 2006 and has stated that during the preparatory phase for this meeting the questionnaires that will be sent to all participants to be completed by them and analysed by the project team, in order to discuss and decide how best to proceed with writing a manual for SOPs.

The project team has asked every participant institution, i.e. the persons named on the A2 registration forms of the proposal, to provide the name and contact details for a "nominated person". All participants returned dedicated names of those individuals that started their work as the primary contact point during the course of the project. (**Annex II - List of nominated persons**). In order to verify the information of all nominated persons, the names and contact addresses where also included in the Survey questionnaire.

All nominated person have been shown during their work in the project to be highly competent in transfusion medicine with knowledge in quality management and are bilingual (native and English) and have been successfully setting-up the multilingual structure of the project and its accompanying documents.

In addition, during the start-up phase the project management team designed the lay-out and the content of the project **internet-based communication platform** (www.eu-q-blood-sop.de), and the information has been divided into a **public and a member area**. The member area is password protected in order to allow the communication of drafted version of documents in between participants. In order to achieve this, the 'document section' in the Web site has been designed to allow each participant to upload his documents. This ensured the communication of results obtained by the different working groups. The project team has the right to modify the document section and the news section using a special webmaster-facility hooked to the project homepage.

3.3 Preparatory phase (EU-SOP Survey)

The **EU-Blood-SOP survey questionnaire (Deliverable D1)** (see Annex IV) has been designed by the project team during the following project work phase. It has been revised and finalised including the comments given by the members of the advisory board (**Communication 2**). Before sending the questionnaire to the participants, the project team performed an in-house validation by giving the questionnaire to individuals from our institution (BSD-BH) and Sanquin (Netherlands). These individuals have been not involved in the process of the questionnaire design.

The results of this validation were used to perform a last fine-tuning of the wording and the structure of questions used in the questionnaire.

The questionnaire has been designed in order to find out the current status of SOPs, their structures and any potential manuals or regulations which are in place in the various participant institutions and countries. In particular, questions where included that have allowed to identify international and national SOP manuals already in place (e.g. by AABB), being used or its use being legally required. One question has been designed, whether the blood establishments have been inspected by government authorities and at what intervals. The awareness of inspections as required by the European Directive 2002/98/EC where relevant has been solicited.

The questionnaire has been set-up in English and has been divided into four different sections specifically addressing questions related to

(I) basic validation,
(II) principal management requirements,
(III) the areas of work, where SOPs are in place, i.e. donor recruitment, testing, management, logistics, etc.
(IV) the way that risks are identified and managed.

These sections were named specifically as follows:
- Section I: **Basic validation**
- Section II: **Principle management requirements**
- Section III: **Working areas (technical)**
- Section IV: **Areas of interest and risk** (referred to the 4 working areas)

The questionnaire has been sent-out by the project team to all participants via e-mail including a participant ‘anonymous’ coding system (**Communication 3**). This coding system has been chosen to guarantee, that the results will be given after evaluation without discriminating individual participants.

During the following phase the project team has been consulted the advisory board by e-mail correspondence and telephone conferences on the relevant quality contents of the documents and project deliverables generated during the project, starting with the questionnaire.

The participants could obtain help in completing the questionnaire by e-mailing or telephoning the project team. The project team has been actively working to get the questionnaires returned in time and completed.

Subsequently all results have been analyzed by the project team compiling the responses into a working document and preparing an evaluation summary (PP1 and PP2, Annex IV) in order to discuss the results with the participants at the first project meeting.

The questionnaire was also used to finalize the detailed information on all participants and nominated persons involved in the project and to use this information for the projects homepage (member section) for optimal communication between the participants.

By the end of November 2005 the most actual information has been collected and was included in the projects homepage. Early in December 2005 a final information (**Communication C4**) letter was sent to the participants giving the project's homepage password and also including the 1st project meeting information in the project's homepage including the possibility to register via the homepage by using a meeting registration form, that could be downloaded (Annex IV).

During January 2006 the project team has defined a list of minimum requirements for SOPs that a blood service needs to cover in order to produce it owns SOPs. The content of these principles and SOP drafts (PP3, Annex IV) have been discussed and partly modified during the following 1st Project Meeting.

3.4 First Meeting phase

The preparation for the 1st Project meeting was finalized in the first half of January booking all hotel facilities, arranging for catering, technical equipment and room facilities in the blood establishment in Frankfurt (DE). A final **communication 5** was sent to all of those participants being late in registration for the hotel rooms.

Finally, the project team could welcome to the 1st project meeting all partners, including the project team, the advisory board members, the working group leaders, the working group members, and as an official representative from the European Commission, Dr. E. Fernandez-Zincke, and as an observer, Frances Delaney (former EC representative) (PP4, Annex IV). Travel expenses of the working group leaders and members as well as the advisory board were covered by the project. Special travel reimbursement forms were provided on the Projects homepage and during the meeting. The meeting lasted 2 1/2 days and was used to

- review the background of the project and its objectives (project team)
- identify the link with the EU blood legislation (EU representative)
- present the results of the survey questionnaire
- identify the principle management and technical areas to be developed
- present the SOP backbone structure and form working groups to further develop it
- agree on the distribution of work activities among participant establishments and the 'modus operandi' (e.g. formation of working groups, determination of the sites for working group meetings, and timetables for these meetings).
- table and adopt the EU SOP survey report at the First project meeting.

A **meeting summary report** and the **EU-SOP survey report (Deliverable D2)** has been written during February and March including the comments given by the participants. The meeting report also comprises the first outline of the

Manual structure (chapters) and included documents (see D3 and D3-1, D3-2, D3-3, D3-4, D3-5, D3-6).

The EU-Q-Blood SOP Survey Report itself has been divided in

- (Part I) Basic Validation
- (Part II) Principle Management requirements
- (Part III) Working areas (technical)
- (Part IV) Areas of interest and risk.

All results were analyzed and published using a participating member code Q-SOP-xxx-yy (where xxx = centre and yy = region [established / new / EEA/EFTA / applicant]).

The project meeting report contains also a consensus document describing the structure of the working groups finally defined during the 1st project meeting and the further work of the project (work group SOP topics, test sites, etc).

The formation of working groups was based on the Project's working plan. It did also include the individual skills of the participating services. For each working group one leader was assigned as defined in Annex I of the Project. Following the skills and interests of the participants the working groups were formed containing 4-5 participants, with the exception of working group IV were in addition to the working plan the Scottish blood transfusion service joint as an observing member. Beside the formation of the working groups and the definition of a sample SOP topic, the test sites for the sample-SOPs were defined between the working group members.

The participants agreed also on a joint working plan for the upcoming manual drafting phase conducted by the working groups. This working phase comprised

- a detailed process analysis of the SOP topic between the individual participants of each working group,
- a delta-analysis by exchange of the currently used processes in between the working group participants
- definition of a simple process (flow chart) covering the critical quality activities (risk ID)
- the definition of SOP requirement (1 or several) or relation of the processes described to general quality management policy documents
- writing of the sample SOP (at least one) including the basic quality elements to be addressed.

The results of the different working groups were decided to be exchanged before the 2nd WG meeting in June 2006. In addition to this process the project team has drawn up definitions from the Directives to be included in the final SOP manual.

Working group 1 (WG 1): Logistics, storage, distribution, management	
The Netherlands (Leader), Cyprus, Iceland, Italy	
SOP-Topic	**Identification of donors and labelling**
1st WG-Meeting	23rd to 24th of March, ISS, Rom (Italy)
Test site	Cyprus
Areas of Interest and Risk identified	**-** Blood Collection - Donor Identification - Donor acceptability/selection/interview - Disinfection and Sterility of blood components - Labelling and Identification

Working group 2 (WG 2): Testing (Immunohematology, Molecular Diagnostics)	
United Kingdom (Leader), Belgium, Bulgaria, Romania	
SOP-Topic	**Blood Group determination and compatibility testing in emergency**
1st WG-Meeting	23rd to 24th of March, NBS, London (UK)
Test site	Bulgaria
Areas of Interest and Risk identified	- Testing of blood groups and labelling (Rhesus variants/ABO) - Testing in emergencies - Donor registries (could be linked to Section IV)

Working group 3 (WG 3): Special blood component production	
Germany (Leader), Czech Republic, Hungary, Malta, Poland	
SOP-Topic	**Processing of platelet apheresis concentrates**
1st WG-Meeting	11th – 12th of May, HBTS, Budapest (HU)
Test site	Malta
Areas of Interest and Risk identified	**-** Apheresis Concentrates (Platelets) - Pooled Platelet Concentrates - Granulocyte Concentrates - Pediatric Units

Working group 4 (WG 4): Logistics, storage, distribution and management	
France (Leader), Estonia, Ireland, Scotland	
SOP-Topic	**Validation of temperature control areas for storage and transportation of blood components**
Additional Guidelines	**Change control of documents**
1st WG-Meeting	13th – 14th of April, IBTS, Dublin (IR)
Test site	To be defined
Areas of Interest and Risk identified	- Transportation and temperature control - Validation of equipment - Central blood stock management and distribution - Blood component release and/or issuing - Storage and transport related to production

3.5 Manual drafting phase

Following the 1st project meeting the participants started to draft sample SOPs as defined during the 1st project meeting on particular topics of interest. This work was conducted by the working group leaders (Christian Seidl (BSD-BH), Petra d´Herminez (Sanquin), Alan Slopeki (NBS), Leslie Sobaga (EFS)) in cooperation with the project team in Frankfurt. Four working group meetings (each working group one meeting) were organized by the working group leaders and hosted by the participants from ISS (IT), HBTS (HU), IBTS (IE) and NBS (UK).

This work included also guidelines for the change control of SOPs as decided by the project participants during the 1st project meeting.

The SOPs were written in order to draft the final manual and to harmonize the various formats used by the participants in writing SOPs. The framework SOP documents presented by the project team and discussed by the participants during the 1st project meeting in Frankfurt were fine-tuned by the working groups during March 2006 and published in the member area, document section, of the project homepage (D3, D3-1, D3-2, D3-3, D3-4, D3-5, D3-6).

During this phase, the working groups were focused on specific selected areas covering their working group areas:

(1) donor recruitment, blood collection, standard blood component production and testing
(2) immunohematology and molecular diagnostics (blood group and virus testing)
(3) special component production
(4) logistics, storage, distribution and management.

This work was done in parallel by the members of the project team and the nominated persons involved in the working groups, with each working group addressing a specific area.

The drafts (D4) addressed
a) general aspects in SOP writing
b) specific aspects regarding structural elements of an SOP.

These included (D4)

- D4-1 **Identification of donors and labelling**
- D4-2 **Blood Group determination and compatibility testing in emergency**
- D4-3 **Processing of platelet apheresis concentrates**
- D4-4-1 **Validation of temperature control areas for storage and transportation of blood components**
- D4-4-2 **Change control of documents (Guidelines)**

Among point (b), there were chapters on the definition of personal responsibilities (qualification and job descriptions) and structural transparency (flow-charts), authorization and change control of documents, overall methodology and process description, structural break-down of methods and processes in order to define quality relevant checkpoints, best practice quality requirements (e.g. in-process controls/internal quality standards), and on how to address priority risk considerations.

All SOPs were published in the 'document section' of the project homepage before the 2nd Working group meeting, that has been organized by the BSD-BH as a joint working group meeting in Frankfurt from the 1st to 3rd of June 2006.

During the working group meeting in Frankfurt each working group presented their SOP(s) and the results were discussed by the participants. All participants agreed on the importance of using flow-chart in order to define a certain process or topic that has to be described in an SOP. These flow-charts should by flexible enough to allow for local adaptation, however important specific requisite should be used in order to harmonise the procedure for the manual draft. These were defined as follows:

- usage of international symbols to describe flow-charts
- flow charts should be made in a first step in a simplified manner in order to define the key decision points in an overall work process. In a later step important decision point have to be elaborated using additional flow-charts.
- This approach should also be used to define, if the process should be described in a single SOP or if it would be more convenient to use several SOPs linked to each other to cover the process.

With respect to the content of the SOPs the participants agreed on a minimum list of requirements for the design of an SOP (Figure 2).

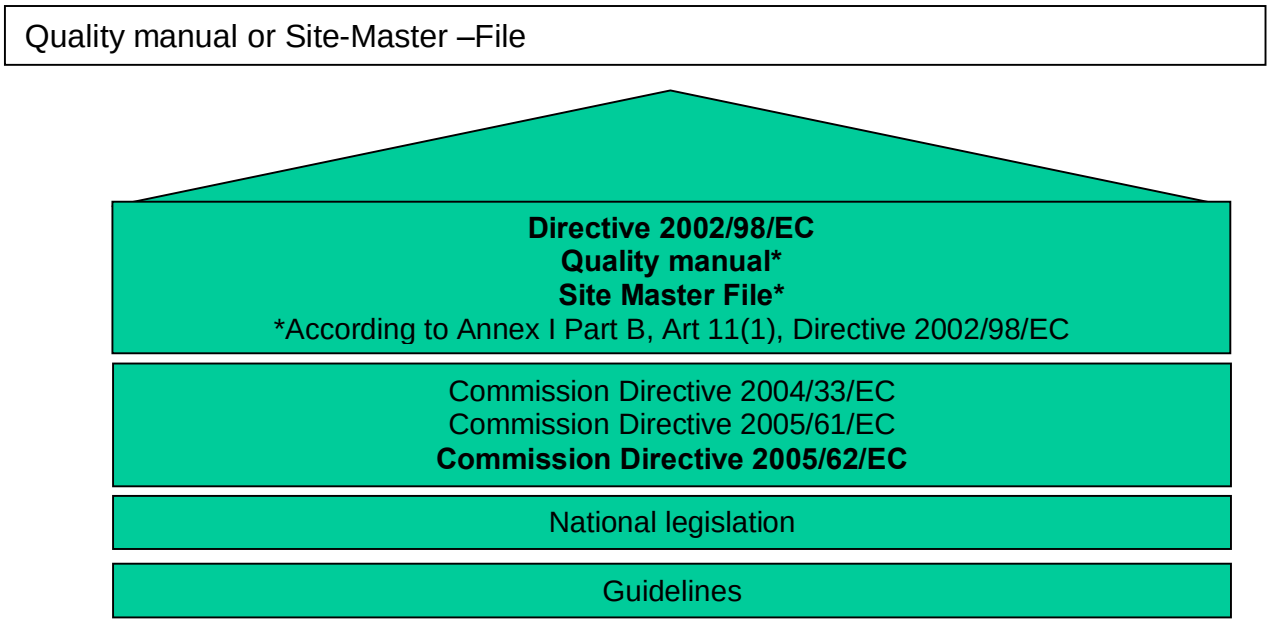

Figure 2: Schematic presentation of the minimum list required by an SOP

All participants emphasized that the SOP level can be sufficient to describe work processes, however these SOPs have to be incorporated in the Quality management system in accordance to Annex I Part B, Art 11(1), of Directive 2002/98/EC. Most of the project participants have additional requirements following GMP regulation and/or ISO standards for setting-up a quality manual (ISO) or Site-Master-File (GMP). Using this structure and the recommendations for the flow-chart concept, the participants have outlined the following principle of a step-wise-analyses of working processes to be described by an SOP system (Figure 3).

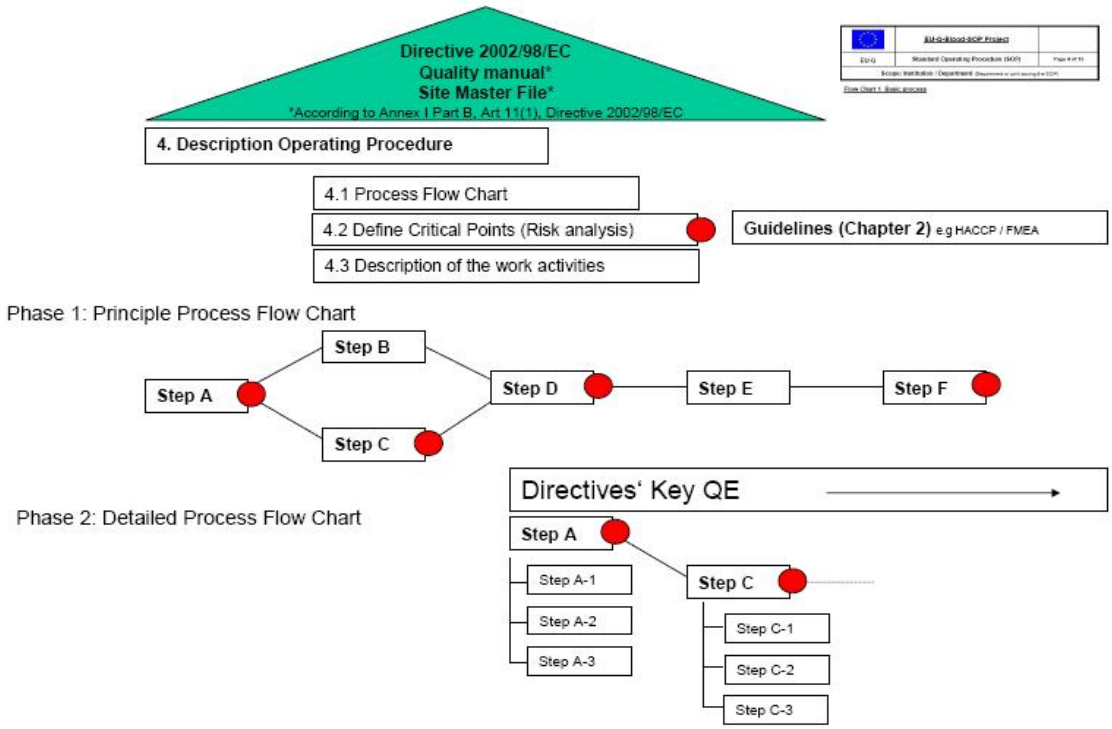

Figure 3: Step-wise-generation of flow-chart and definition of critical point (red points).

3.6 **Test phase**

In order to finalise and adapt the manual during the next period of the project, it was decided to form a '**Manual Drafting Team' (MDT**) that consist of the working group leaders Christian Seidl (BSD-BH, DE), Petra L'Herminez (Sanquin, NL), Leslie Sobaga (EFS, FR), Marie O'Connell (IBTS, IE) and as advisors Frances Delaney (former EU) and Angus McMillan Douglas (Project advisory board). The manual drafting team will finalize the manual using the results of the testing sites. A manual drafting team meeting has been scheduled for the 28th and 29th of November in Frankfurt (BSD-BH, DE).

The **EU-Q-Blood-SOP manual (D5)** has been defined as follows:

Chapter 1: Introduction

Chapter 2: Overview of quality principles linked to the Directive 2005/62/EC

Chapter 3: SOP backbone structure and guidelines for change control

Chapter 4: SOP Examples (WG1-4) covering the critical quality activities in the samples taken from the areas of interest and risk

Annex: Definition of
- key quality terms linked to the Directive 2005/62/EC
- GMP/GLP best practice terms used in the manual

The testing phase will be performed in parallel to the manual drafting and completion in order to allow for a more detailed elaboration of the Manual content. The participating blood establishment in Malta has been already started to redraft several institutional SOPs following the principle structure work-out by the project. This has been in particular helpful, since the Malta partner is aiming at improving his quality management system to cover GMP and ISO regulations. Besides Malta, the participant from Cyprus has been cross-linked to redesign his SOP system.

The project team has updated the working plan, has been completed the financial interim report, the present report and has been actively involved in national and international meetings in the field of blood transfusion (D9).

In these meetings lectures and presentations on the projects objectives and deliverables have been presented to an international auditorium of professional in the field. These lectures have been also used to disseminate the projects 'public area' of the website in order to link interested professional and/or blood establishments to the project. During the 2nd joint working group meeting it has been also agreed by the participants, that each participant will be in the future a 'national' contact point for interested institutions, blood establishments giving help in optimising their SOP system according to the projects objectives.

These presentations and abstract publications as well as the homepage itself have been given clear visibility of the co-funding from the European Commission, Directorate C. The project team has been also offered the possibility by the editorial board of 'Transfusion Today' to write a publication on the project's deliverables. This publication is currently prepared and will be submitted to the journal beginning of November.

3.7 Publications

EU-Q-Blood-SOP: Development of pan European quality management in transfusion medicine. C Seidl, E. Schellenberg, R. Henschler, A. McMillan Douglas, CS SMit Sibinga, M. Gorham, M. Letowska, J. DeWit, E. Seifried. Abstract Presentation International Society of Blood Transfusion (ISBT); *Vox Sanguinis*, Vol 93 (Suppl 3) 2PS-01-03, p6, 2006

European Quality Management in Transfusion Medicine. C Seidl, E. Schellenberg, R. Henschler, A. McMillan Douglas, CS SMit Sibinga, M. Gorham, M. Letowska, J. DeWit, E. Seifried. Abstract Presentation Joint Congress German Society of Transfusion Medicine and Immunohematology (DGTI) with the International Society for Cellular Therapy (ISCT), *Transfusion Medicine and Hemotherapy*, Vol 33 (Suppl 1), OS6.1, p14, 2006

EU-Q-Blood-SOP: A European initiative developing quality management criteria. Abstract Presentation 14th Annual Congress of the German Society for Immunogenetics (DGI), *Meeting Proceedings*, P13, p38, 2006

Publication in Preparation for *Transfusion Today*, November 2006

Annex I

Project Participants, Blood Establishments and Institutions

Red Cross Blood Donation Service Baden-Württemberg-Hessen
with its head office in Frankfurt am Main (GERMANY)
Prof. Dr. med. Erhard Seifried,
Medical Director and CEO
Institut für Transfusionsmedizin und Immunhämatologie
Sandhofstrasse 1
60528 Frankfurt am Main

The National Blood Authority
(England and North Wales) established in Watford, Herts (UNITED KINGDOM)
Martin Gorham
National Blood Service
Oak House, Reeds Crescent
WD24 4QN
Watford, Herts

Stiching Sanquin Bloedvoorziening
(Sanquin Blood Supply Foundation) established in Amsterdam (THE NETHERLANDS)
Dr. Jeroen De Wit
Sanquin Blood Supply Foundation
Plesmanlaan 125
1066 CX Amsterdam

Etablissement Français du Sang
established in Paris (FRANCE)
Prof. Dr. Patrick Hervé
Etablissement Français du Sang (EFS)
100, Avenue de Suffren
75015 Paris

Het Belgische Rode Kruis
established in Brussels (BELGIUM)
Prof. Dr. Philippe Vandekerckhove
Dienst voor het Bloed, Rode Krius-Vlaanderen
Vieurgatsesteenweg 98
1050 Brussel
Mailing address: Motstraat 40, 2800 Merchelen

The Blood Transfusion Service Board
established in Dublin
Dr. William Murphy
Mr. Andrew Kelly, CE
Irish Blood Transfusion Service
National Blood Centre
James´s Street
Dublin 8 Dublin

Istituto Superiore di Sanita
established in Rome (ITALY)
Prof. Dr. Enrico Garaci, President
Dr. Hamisa Jane Hassan
Instituto Superiore di Sanita
Blood Transfusion Methodology Section
Department of Hematology, Oncology and Molecular Medicine
Viale Regina Elena 299
00161 Rome

НАЦИОНАЛЕН ЦЕНТЪР ПО ХЕМАТОЛОГИЯ И ТРАНСФУЗИОЛОГИЯ
(National Center of Hematology and Transfusiology) established in Sofia (BULGARIA)
Prof. Andrey Andreev, MD, PhD, Director
National Center of Haematology and Transfusiology
Plovdivsko Pole Str. 6
1756 Sofia

VSEOBECNÃ FAKULTNÍ NEMOCNICE V PRAZE
(University Hospital of Prague) established in Prague (CZECH REPUBLIC)
MuDr. Pavel Horak, CSc., MBA
Vseobecná fakultní nemocnice (General Teaching Hospital)
U Nemocnide 2
128 08 Praha 2

Orszàgos Vèrellàtò Szolgàlat
(Hungarian National Blood Transfusion Service) established in Budapest (HUNGARY)
Dr. Klára Baróti-Tóth, Ph.D.
Hungarian National Blood Transfusion Service
Quality Assurance Department
Karonlina str. 19 - 21
1113 Budapest

Instytut Hematologii I Transfuzjologii
(Institute of Hematology and Blood Transfusion) established in Warsaw (POLAND)
Doc. Dr. Med. Magdalena Letowska
Prof. Dr. Krzysztof Warzocha, Director
Marianna Joriska, MSc
Institute of Haematology and Blood Transfusion
Department of Blood Transfusion
Chocimska 5
00-957 Warsaw

Universitatea de Medicina si Farmacie "Victor Babes" Timisoara
(University of Medicine and Pharmacy "Victor Babes" Timisoara established in Timisoara (ROMANIA)
Prof. Dr. Virgil Paunescu
Prof. Dr. med. Dan Poenaru
University of Medicine and Pharmacy
"Victor Babes" Timisoara
Physiology and Immunology
Uta loan Colonel Martir No.2
300041 Timisoara

Põhja-Eesti Verekeskus
(North-Estonian Blood Centre) established in Tallin (ESTONIA)
Dr. Tatjana Plahhova, MD
North-Estonia Blood Centre
Ädala 2
10614 Tallinn

Υπουργείο Υγείας της Κυπριακής Δημοκρατίας - Ιατρικές Υπηρεσίες κσι Υπηρεσίες Δημόσιας Υγείας
(Ministry of Health of the Republic of Cyprus - Medical and Public Health Services) established in Lefkosia (CYPRUS)
Dr. Stala Kioupi
Dr. Androulla Agrotou, Acting Director
Medical Services and Public Health Services
Ministry of Health Cyprus
10 Marcou Drakou, Pallouriotissa
1449 Lefkosia (Nicosia)

Landspitalinn Hàskòlasjuùkrahùs
(Icelandic University Hospital) established in Reykjavik (ICELAND)
Dr. med. Sveinn Gudmundsson
Torfi Magnusson, MD, CEO
Landspitalinn Hàskòlasjuùkrahùs
Icelandic University Hospital
Blood Bank
Baróstig
101 Reykjavik

Centru Nazzjonali ta't-Trafuzjoni tad-Demm
(National Blood Transfusion Service) established in G'Mangia (MALTA)
Dr. Alex Aquilina
National Blood Transfusion Service
St. Luke`s Square
MSD 07 G´Mangia

Annex II

Project Nominated Persons

Red Cross Blood Donation Service Baden-Württemberg-Hessen with its head office in Frankfurt am Main (GERMANY)
Prof Dr. med. Christian Seidl (Nominated)
PD Dr. med. Reinhard Henschler (Nominated)
Dr. Esther Schellenberg
Saman Hosseini
MUDr. Walid Sireis
Institut für Transfusionsmedizin und Immunhämatologie
Sandhofstrasse 1
60528 Frankfurt am Main

The National Blood Authority (England and North Wales) established in Watford, Herts (UNITED KINGDOM)
Alan Slopecki
Head of Quality Assurance
Kirstie Philpot, Personal Assistant
National Blood Service
Crescent Drive
Brentwood
Essex, CM15 8DP

Stiching Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation) established in Amsterdam (THE NETHERLANDS)
Petra L´Herminez
Sanquin Blood Supply Foundation
PO Box 9892
1006 AN Amsterdam

Etablissement Français du Sang established in Paris (FRANCE)
Dr. Alain Beauplet (Nominated Person)
Claudine Hossenlopp, Chargée de mission
Etablissement Français du Sang (EFS)
Direction Affaires Internationales
100, Avenue de Suffren
75015 Paris

Het Belgische Rode Kruis established in Brussels (BELGIUM)
Dr. Inge Buyse
Dienst voor het Bloed, Rode Krius-Vlaanderen
Vieurgatsesteenweg 98
1050 Brussel
Mailing address: Motstraat 40, 2800 Merchelen

The Blood Transfusion Service Board established in Dublin (IRELAND)
Dr. William Murphy
Irish Blood Transfusion Service
National Blood Centre
James´s Street
Dublin 8 Dublin

Istituto Superiore di Sanita established in Rome (ITALY)
Dr. Hamisa Jane Hassan
Instituto Superiore di Sanita
Blood Transfusion Methodology Section
Department of Hematology, Oncology and Molecular Medicine
Viale Regina Elena 299
00161 Rome

НАЦИОНАЛЕН ЦЕНТЪР ПО ХЕМАТОЛОГИЯ И ТРАНСФУЗИОЛОГИЯ (National Center of Hematology and Transfusiology) established in Sofia (BULGARIA)
Svetla Bakalova, MD, PhD
National Center of Haematology and Transfusiology
Quality Assurance Department
6, Plovdivsko Pole Str.
1756 Sofia

VSEOBECNÃ FAKULTNÍ NEMOCNICE V PRAZE (University Hospital of Prague) established in Prague (CZECH REPUBLIC)
Petr Turek, MD, PhD
Vseobecna fakultni nemocnice (General Teaching Hospital)
U Nemocnide 2
120 00 Prague 2

Orszàgos Vèrellàtò Szolgàlat (Hungarian National Blood Transfusion Service) established in Budapest (HUNGARY)
Dr. Klára Baróti-Tóth, Ph.D.
Eszter Miskovits, MD
Hungarian National Blood Transfusion Service
Quality Assurance Department
Karonlina str. 19 - 21
1113 Budapest

Instytut Hematologii I Transfuzjologii (Institute of Hematology and Blood Transfusion) established in Warsaw (POLAND)
Elzbieta Lachert
Institute of Haematology and Blood Transfusion
Department of Blood Transfusion
Chocimska 5
00-957 Warsaw

Universitatea de Medicina si Farmacie "Victor Babes" Timisoara (University of Medicine and Pharmacy "Victor Babes" Timisoara established in Timisoara (ROMANIA)
Dr. Carmen Tatu
Blood Center
P-ta Eftimie Murgu Nr 2
Timisoara

Põhja-Eesti Verekeskus (North-Estonian Blood Centre) established in Tallin (ESTONIA)
Dr. Tatjana Plahhova, MD (Nominated person)
Mrs. Riima Niidas
North-Estonia Blood Centre
Ädala 2
10614 Tallinn

Υπουργείο Υγείας της Κυπριακής Δημοκρατίας - Ιατρικές Υπηρεσίες κσι Υπηρεσίες Δημόσιας Υγείας (Ministry of Health of the Republic of Cyprus - Medical and Public Health Services) established in Lefkosia (CYPRUS)
Ms. Zoe Sideras
Ministry of Health
Medical and Public Health Services
Nicosia General Hospitel
Blood Bank of Nicosia
Nechrou Avenue

Landspitalinn Hàskòlasjuùkrahùs (Icelandic National University Hospital) established in Reykjavik (ICELAND)
Dr. Sveinn Gudmundsson, MD, Director
National University Hospital
The Blood Bank
Blóðbankinn , Landspítali-háskólasjúkrahús
At Barónsstigur
IS-101 Reykjavik
Tel.: +354-543-5530
Fax.: +354-543-5532
E-Mail: sveinn@landspitali.is

Centru Nazzjonali ta't-Trafuzjoni tad-Demm (National Blood Transfusion Service) established in G'Mangia (MALTA)
Dr. Alex Aquilina
Consultant/Responsible Person
National Blood Transfusion Service
St. Luke`s Square
G´Mangia MSD007

Annex III

Financial Interim Report

(enclosed file EU2004217-Financial Interim Report.xls)

Annex IV

Enclosed documents (files) as referred to Time table (see 3.1)

C1 – Communication 1

C2 – Communication 2

C3 – Communication 3

C4 – Communication 4

C5 – Communication 5 Part1

C5 – Communication 5 part 2

D1 – Survey questionnaire

D2-D3 – Survey report and Manual draft

D3-1 – SOP-Master Document Record_DR

D3-2 – SOP-Master Equipment Procedure_EP

D3-3 – SOP-Master-General Procedure_GP

D3-4 – SOP-Master-QMH-Site Master File_QMH

D3-5 – SOP-Master-Working Procedure_WP

D3-6 – SOP-Master-Test Procedure_TP

D4-1 Sample SOP (Working Group I)

D4-2 Sample SOP (Working Group II)

D4-3 Sample SOP (Working Group III)

D4-4-1 Sample SOP (Working group IV)

D4-4-2 Sample SOP (Guidelines) (Working Group IV)

D5 – SOP-Master-EU-Blood-SOP Version 1_0

PP1 – Survey section I-III

PP2 – Survey section IV

PP3 – SOP Framework

PP4 – 1st Meeting

PP5 – 2nd WG Meeting

PP6 – Meeting Project Interim

C1 – Communication 1

C2 – Communication 2

C3 – Communication 3

C4 – Communication 4

C5 – Communication 5 Part1

C5 – Communication 5 part 2

D1 – Survey Questionnaire

D2-D3 – Survey report and Manual draft

D3-1 – SOP-Master Document Record_DR

D3-2 – SOP-Master Equipment Procedure_EP

D3-3 – SOP-Master-General Procedure_GP

D3-4 – SOP-Master-QMH-Site Master File_QMH

D3-5 – SOP-Master-Working Procedure_WP

D3-6 – SOP-Master-Test Procedure_TP

D4-1 Sample SOP (Working Group I)

D4-2 Sample SOP (Working Group II)

D4-3 Sample SOP (Working Group III)

D4-4-1 Sample SOP (Working group IV)

D4-4-2 Sample SOP (Guidelines)

(Working Group IV)

D5 – SOP-Master-EU-Blood-SOP Version 1_0

PP1 – Survey section I-III

PP2 – Survey section IV

PP3 – SOP Framework

PP4 – 1st Meeting

PP5 – 2nd WG Meeting

PP6 – Meeting Project Interim