



## CHALLENGES IN AUDITING SUPPLIERS, BE PERSPECTIVE

*Stéphane Bégué, Etablissement Français du Sang (EFS), France*

Keeping up with reality and Quality: a challenge for European Blood Establishments  
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## WHY SHOULD WE PERFORM SUPPLIER AUDITS?



### GOOD PRACTICE GUIDELINES

For Standards and Specifications for Implementing the Quality System in Blood Establishments

#### 4.7. Control of equipment and materials

4.7.1. General principles

4.7.1.2. The contracting process should include:

4.7.1.2.5. regular contact with suppliers to help understand and resolve problems;

4.7.1.2.6. performance of regular **audits**.

#### 6.2. Collection of blood and blood components

6.2.14. Where the blood is not transported by the processing establishment itself, the responsibilities of the transport company should be clearly defined and periodic **audits** should be conducted to ensure compliance.

## WHY SHOULD WE PERFORM SUPPLIER AUDITS?

### Supplier audit – for what?



To mitigate supply chain risks by checking that suppliers and contractors are suitable to provide a sustainable supply of various goods or services.

### Supplier audit – what should be evaluated?



- Economics and finance ?
- Quality management ?
- Social: health, safety, ethics and the environment ?
- Manufacturing processes?

## WHY SHOULD WE PERFORM SUPPLIER AUDITS?

### What are the benefits of suppliers audit ?



***And also because, you don't take everything they say for granted !***

## WHY SHOULD WE PERFORM SUPPLIER AUDITS?

*But also....*



## WHAT ARE THE REQUIREMENTS.... AND THE NEEDS ?

*When ?*

**On a regular basis ⇒ Every 4 years at EFS**

**On crisis situations**

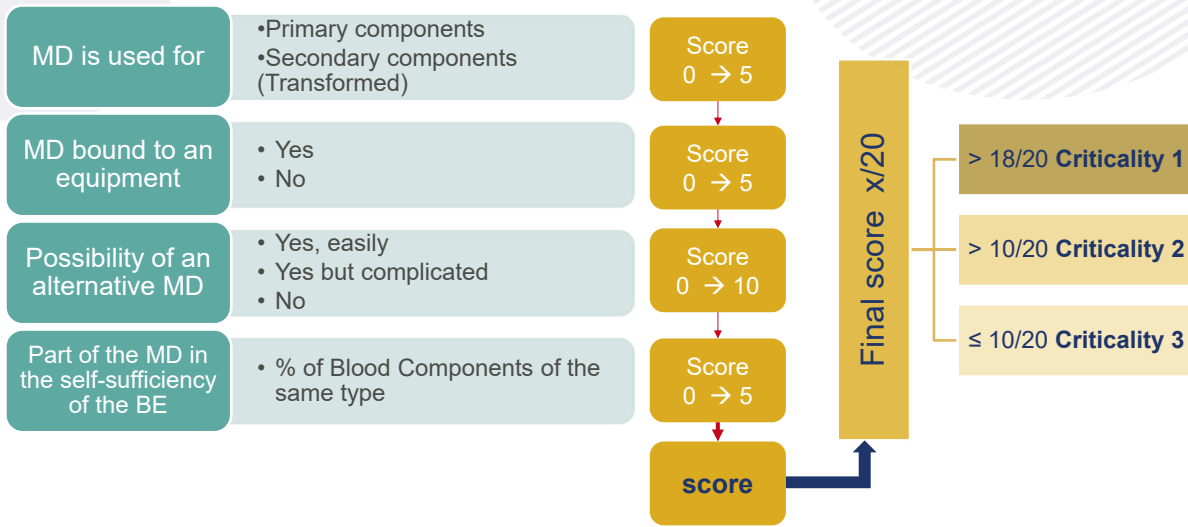
- **Major issues on Product Quality**
- **Breached confidence**

**Major changes in production process or location**

**New critical supplier**

## ARE ALL SUPPLIERS WORTH AUDITING?

How did we solve the criticality question at the EFS? → An example on Medical devices for Blood Components



## LIST OF SUPPLIERS FOR PRODUCTION OF BLOOD COMPONENTS

**cerus**

**FRESENIUS KABI**

**HAEMONETICS®**

**macopharma**  
DESIGNED FOR LIFE

**TERUMOBCT**

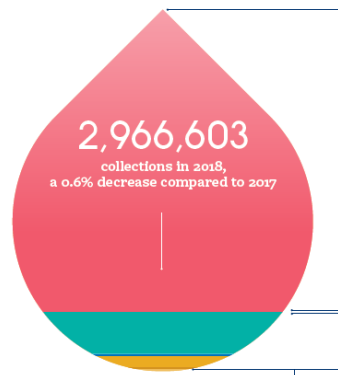
Are all critical supplier for the EFS and are regularly audited on site

***Thank you for accepting and proactively collaborating with EFS audits !!!!***

# WHAT ARE THE REQUIREMENTS.... AND THE NEEDS



What are the benefits of suppliers audit ?



**BLOOD COLLECTIONS**  
**2,512,879**  
collections (0.6% increase)  
**INCLUDING**  
**2,512,870**  
allogeneic collections (0.6% increase)  
**AND**  
**9**  
autologous collections (78% decrease)



**8,429**  
private sector employees

**432**  
seconded civil servants

**54**  
seconded employees

**5**  
public sector contractors

**797**  
temporary workers



EQUIVALENT TO

**344,461** (9.5% decrease)  
Single-product apheresis

**109,263** (4.1% increase)  
combined apheresis



# WHAT DOES IT TAKE TO PERFORM SUPPLIERS AUDIT ?



Auditor Resources

**62 National Auditors,**  
**40 are qualified Lead Auditors**

**50 experts**  
**covering all activities**



⇒ **13 perform on-site Suppliers Audit (4 ICA auditors)**



# WHAT DOES IT TAKE TO PERFORM SUPPLIERS AUDIT ?



## ORGANISATION

Example of a Medical Device for transfusion Supplier with 2 PU abroad

Preparation 1 Day

Site 1

Site 2

Travel D1

Audit 1,5 Days

Travel D3

Audit 2 Days

Travel D5



Audit Report 2 Days

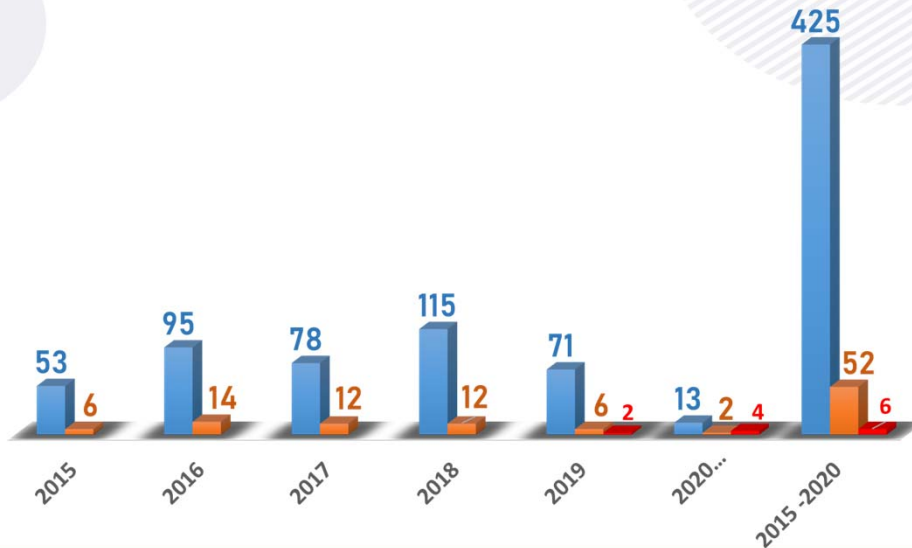
8 to 10 days on full commitment on the audit for 2 auditors

# WHAT DOES IT TAKE TO PERFORM SUPPLIERS AUDIT ?



Activity

■ Internal audits ■ On site Supplier audits ■ e-Audits



## WHAT DOES IT TAKE TO PERFORM SUPPLIERS AUDIT ?



### Audited Suppliers

2015	2016	2017	2018	2019	2020 (non finalisé)
<ul style="list-style-type: none"> <li>• BIOTRANS</li> <li>• FLANDRE</li> <li>• ATELIER</li> <li>• TEXCELL</li> <li>• SGS</li> <li>• LifeSciences</li> <li>• ACM Pharma</li> <li>• TERUMO</li> </ul>	<ul style="list-style-type: none"> <li>• CERBA</li> <li>• FRESENIUS (x2)</li> <li>• ACTEMIUM</li> <li>• CERUS</li> <li>• MACOPHARMA</li> <li>• INGEN</li> <li>• HAEMONETICS (x2)</li> <li>• TERUMO</li> <li>• CORNING</li> <li>• HYCLONE / GE</li> <li>• BIOMERIEUX</li> </ul>	<ul style="list-style-type: none"> <li>• TERUMO</li> <li>• MERCK</li> <li>• MILLIPORE</li> <li>• CRYODIFFUSION</li> <li>• BECKMAN</li> <li>• COULTER</li> <li>• BIORAD</li> <li>• HAEMONETICS</li> <li>• CORNING</li> <li>• FRESENIUS</li> <li>• VIAL (X2)</li> <li>• WAK CHEMIE</li> <li>• ARISTA</li> <li>• TSE/BIOTRANS</li> </ul>	<ul style="list-style-type: none"> <li>• HAEMONETICS</li> <li>• SETCARGO</li> <li>• TLS</li> <li>• ETIQUETTE</li> <li>• EUROBIO</li> <li>• EUROSIN</li> <li>• AIR LIQUIDE</li> <li>• SANTÉ</li> <li>• FRESENIUS</li> <li>• BIORAD</li> <li>• DIAGAST</li> <li>• BACTUP</li> <li>• TECAN</li> <li>• CERUS</li> </ul>	<ul style="list-style-type: none"> <li>• GRIFOLS</li> <li>• SGS</li> <li>• VITROLOGY</li> <li>• TAKARA</li> <li>• GEOPARTS</li> <li>• MPS</li> <li>• WESTROCK</li> <li>• HANDIPRINT</li> <li>• BIOLUZ</li> </ul>	<ul style="list-style-type: none"> <li>• NITTA GELATIN</li> <li>• SNDI (X2)</li> <li>• MACOPHARMA</li> <li>• LBM (X2)</li> </ul>

**2015 – 2020: 41 Suppliers and 58 audits**

## WHAT ARE THE BENEFITS FOR EFS....AND THE SUPPLIER



### Better mutual understanding of supplier constraints and EFS needs.

The message goes beyond BU to directly reach the PU.

### Discovery of major non-conformities

- Unsatisfactory preparation conditions (Hygiene, cleanliness) or risk assessment.
- Non-compliance with contractual commitments
- Inappropriate social working conditions
- Inefficient Customer complaint management and CAPAS
- Poor subcontracting activities and control



**5% of audits needed a verification audit within 6 month.**

**Generally, corrective actions are implemented fast and efficiently**



## SO HOW DO WE SOLVE THE EQUATION FOR SMALL AND MEDIUM SIZE BE

	Regulation and efficiency	HR and financial resources	Supplier perspective
Subcontracting	?	✗	✗
e-audits	?	✓	?
Call for retired auditors (-> ex. EFS)	✓	?	✗
Share reports – field to be defined.	✓	✓	?
<b>Joint audits</b> <ul style="list-style-type: none"> <li>• Between BE of the same country or</li> <li>• International through a cooperation, within a organisation (i.e. EBA)</li> </ul>	✓	✓	✓

## SO HOW DO WE SOLVE THE EQUATION FOR SMALL AND MEDIUM SIZE BE

How could we manage to Join our audit potential ?

### Attention points considering Joint audits

- Don't focus only on the quality system
- Send experts !
- Preparation is central as each country participating must see it's requirements taken into account
- Merge tenders could be solution... but also a weakness point considering business continuity and supplier ecosystem.
- Would joint audits be accepted by Competent authorities?







## THANK YOU FOR YOUR ATTENTION!

*Stéphane Bégué, Etablissement Français du Sang (EFS), France*  
*[stephane.begue@efs.sante.fr](mailto:stephane.begue@efs.sante.fr)*  
*(+33) 6 75 66 73 96*



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