



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.

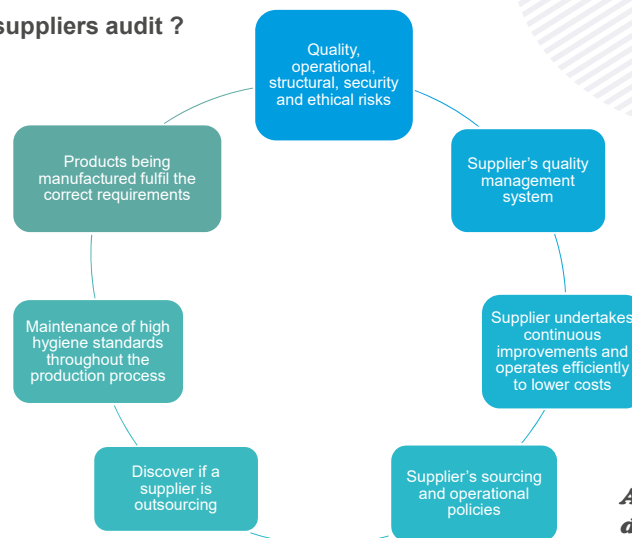
Supplier audit – what should be evaluated?



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

WHY SHOULD WE PERFORM SUPPLIER AUDITS?

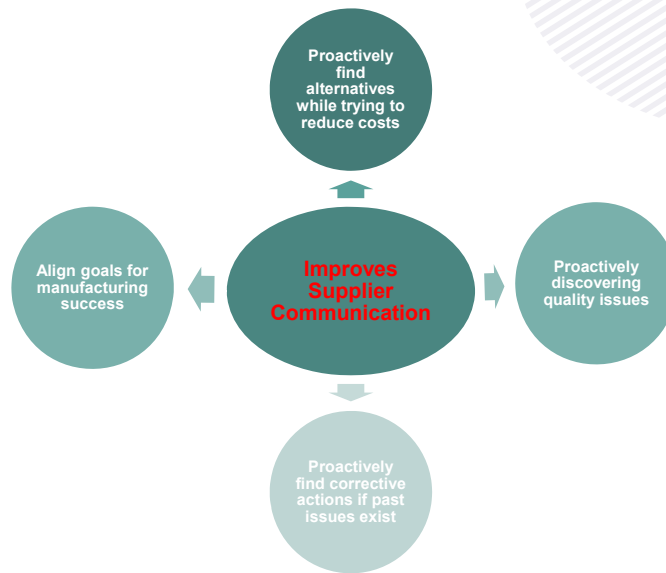
What are the benefits of suppliers audit ?



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

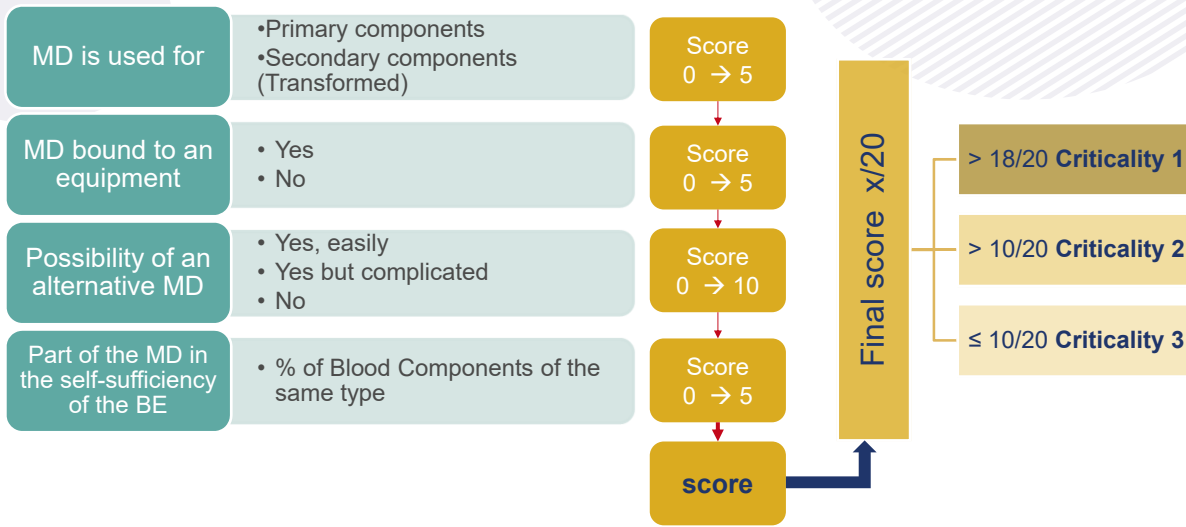
- **Major issues on Product Quality**
- **Breached confidence**

Major changes in production process or location

New critical supplier

ARE ALL SUPPLIERS WORTH AUDITING?

How did we solved 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

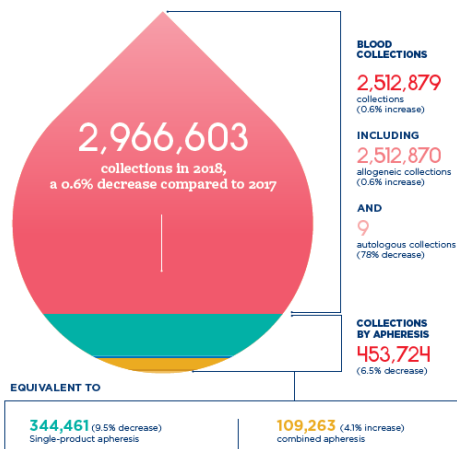
TERUMOBCT

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 ?



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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)



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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



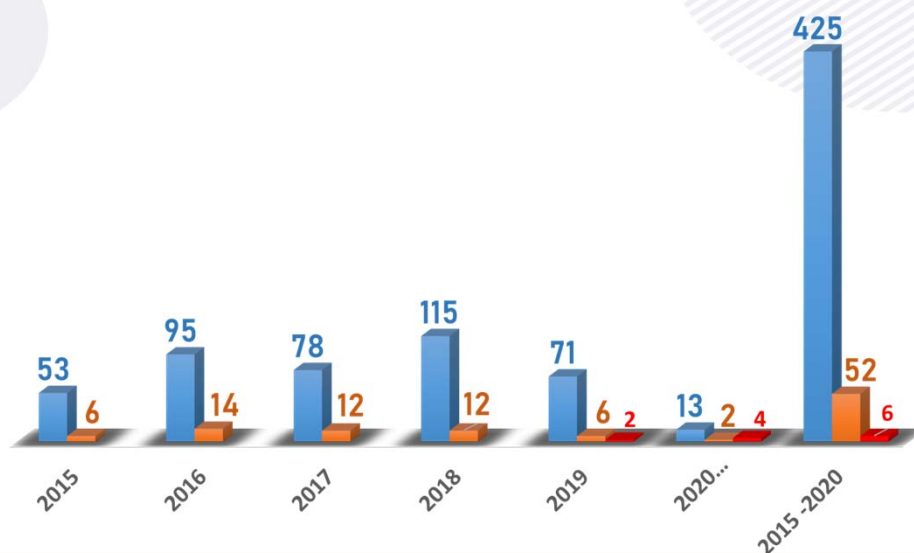
Audit Report 2 Days

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

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.	✓	✓	?
Joint audits <ul style="list-style-type: none"> Between BE of the same country or International through a cooperation, within a organisation (i.e. EBA) 	✓	✓	✓

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
(+33) 6 75 66 73 96



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