



## Greek experience with the EDQM B-QM Programmes

*Keeping up with Reality and Quality: A challenge for European Blood Establishments*

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" AGIOI ANARGYROI"  
GREECE



## Background Information for Greece Blood sector

- **EKEA (HNBTC)** is the **CA** on blood and blood products under the supervision of **MoH**. It is responsible for coordination as well as scientific and technical control of the **National Blood System**.
- At the **end of 2008**, the implementation of the structural and organizational requirements foreseen within the Qualification Process of the **Hellenic Blood System** begun in compliance with both the National and European legislation related to blood and blood components (2002/98/EC, 2005/62/EC, 2005/61/EC, 2004/33/EC) and **today** the **screening for infectious markers** is nationally performed in **2 Centers**.



## Background Information for Greece Blood sector

▪The **Blood Supply System** still remains **decentralized & basically hospital-based**. Mostly all of the **97** Hospital Blood Banks perform recruitment of donors, blood collection, blood grouping, cross matching and transfusion (BEs).



www.ekea.gr

▪Nationally **510.111 units** were collected in 2019 and **120.000** of them are transfused to **thalassemia patients** (*E.KE.A, Dr Stamoulis, personal communication*).

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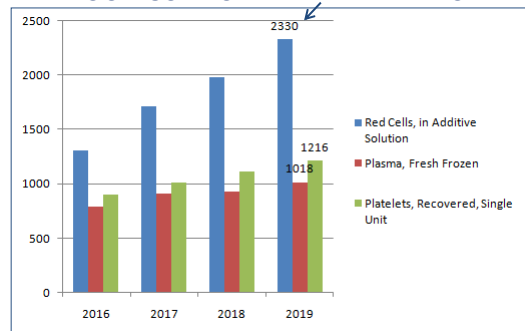


## Background- Who we are

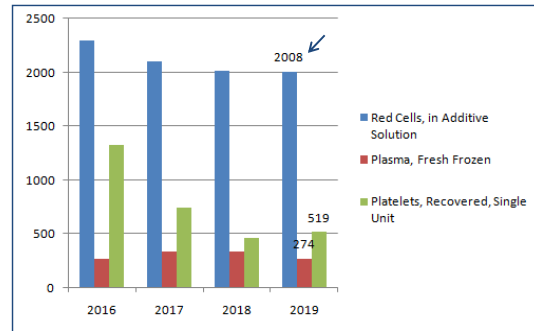
- "OI AGIOI ANARGYROI " Transfusion Service operates as a Hospital Blood Bank since 2010, in a partially teaching 300 bed hospital.
- Blood collection both in our premises and in mobile sites was started in 2015.
- Current work load:



**BLOOD COMPONENT PREPERATION**



**BLOOD COMPONENT TRANSFUSION**



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## OUR LONG JOURNEY TOWARDS QUALITY & SAFETY

- 2016
  - 2 members of our department were qualified as ISO 9001 certification body assessor (ISO 9001 Auditor/Lead Auditor, 5-day CQI and IRCA certified course )
- 2017
  - Certification on ISO 9001-2015 (TUV HELLAS):
    - Scope; Blood Transfusion Services (Collection, Processing, Test and Issue). Hospital based Transfusion Activities and Patient Blood Management Practice to In- & Outpatients.
    - Internal audits: at least once per year
    - External inspection –TUV :yearly (1 inspector, 8 working hours)
- 2018
  - EDQM B-MJV Audit - 3 auditors, 2½ days
- 2019
  - Certification on ISO 15189 (Hellenic Accreditation System SA)-«ESYD»)
- 2019
  - CA E.KE.A External audit (3 inspectors: 1 external legally trained auditor, 2 E.KE.A personnel with relevant competence, 8 working hours), the report is still pending

## HOW WE HEARD ABOUT THE B-QM PROGRAMME

- **Training Course:** European Conference on Sharing best practices: 17-19 October 2017, Strasbourg, France
- **Alexandroupolis Blood Establishment** previous experience (*Dr Martinis, personal communication*)
- **BLOOD-QUALITY MANAGEMENT PROGRAMME** (*Observe the QMS under development and give on site training /recommendations/advice for improvement and/or implementation of the QMS*):
  - does not supersede/replace inspections performed by authorities
  - open to all European blood establishments
  - free of charge
- Application was submitted for **B-MJV** in 2017: Check compliance with requirements, report & recommendations
- Aim: to help improving our newly established QMS

## THEY SAID YES

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- The audit was scheduled in November 2018
- **3 auditors for 3 days !!!???**
- ✓ We mobilized our courage and humour (with a minimum of seriousness)
- ✓ We decided to be:

open and honest,

not to hesitate asking questions,

and to enjoy the whole process

!!!Oh MY  
GOD



## HOW WAS THE AUDIT EXPERIENCED BY THE PERSONNEL?

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- The personnel experienced the audit and supervision as follows:  
*“Audits we had before were not as **demanding**, and did not force us to evaluate our day-to-day work in the same ways [...]”*
- The personnel also endorsed the **managerial-centered focus** and the **focus on potential system deviations** at higher organizational levels



## CREATED AWARENESS



### B-MJV020 Closing Meeting

Nea Kifissia, Athens  
Greece

Auditors: M-L. Hecquet, A. Aquilina,  
L. Montrasio, B. Rothe



The experts brought out difficulties in our **understanding** of the quality concepts in implementing requirements and developing an integrated QMS.

### B-MJV020-Preliminary Report- Observations:

- RM is not **embedded** in the Quality management System
- Evidence of practical implementation of RM is missing.
- RM is currently implemented **solely** in the context of CAPA.
- Personnel do not have a full of Risk Management

## WHAT DID THE PERSONNEL LEARN FROM THE REPORTED DEVIATIONS?

- The audit brought attention to our Quality System deficiencies and was perceived as a **catalyst** for further quality improvements.

“.....but registration of the deviation on the equipment logbook was made only on the 6th of November”



### B-MJV020-Preliminary Report- Observations:

“Several significant temperature deviations occurred during the month of August, September, October and November 2018.....”

“Boxes used by mobile site to storage blood donations are not validated.  
Data logger are not calibrated qualified.  
Flat cooling devices are not qualified.”

# CREATED AWARENESS

## Number and scope of B-MJV report recommended changes:

- major 17
- minor 26

The audit generated the need to work **systematically** in implementing clinical and laboratory practice changes and to sustain these changes.

1	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	Α/Α	ΗΜΕΡΑ ΣΥΜΒΑΝΤΟΣ	ΗΜΕΡΑ ΜΕΤΡΗΣΗΣ	ΚΩΔΙΚΟΣ ΣΥΜΒΑΝΤΟΣ	ΑΙΤΙΑ	ΚΑΤΗΓΟΡΙΑ	ΜΟΝΑΔΑ	ΕΙΔΟΣ	ΠΕΡΙΓΡΑΦΗ	ΚΩΔΙΚΟΣ	ΤΥΠΟΣ	ΕΠΙΣΤΑΣΗ	ΕΠΙΤΥΧΗ	ΠΡΟΣΤΑΣΙΑ	ΑΝΑΦΟΡΑ	Ν/Σ	ΤΥΠΟΣ ΚΑΤΑΣΤΑΣΗΣ	
84	83	20/11/18							ΚΑΤΑΓΡΑΦΗ ΠΟΙΟΤΙΚΟΥ ΕΛΕΓΧΟΥ	AA07	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	PLAN	
85	84	14/12/18		OKI			18002895, 18002896	ΣΕ Μ	ΛΑΝΘΑΣΜΕΝΗ ΚΑΤΑΚΟΡΨΗΝ ΕΡΓΑΣΤΗΡΙΑΚΩΝ ΕΙΣΤΑΣΕΩΝ	AE03	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	ΠΟΑ		ΣΚΑΕ			
86	85	07/01/19	1-M1						ΑΡΜΟΔΙΟΤΗΤΕΣ ΠΡΟΣΩΠΙΚΟΥ- ΟΡΓΑΝΟΓΡΑΜΜΑ	AA03	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
87	86	07/01/19	2-M2						ΕΛΕΓΧΕΙΣ ΣΔΠ (RM, CC, VALIDATION)	AA13	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
88	87	07/01/19	3-M3						ΣΥΣΤΗΜΑ ΤΕΚΜΗΡΙΩΣΗΣ ΕΛΕΓΧΟΥ ΕΝΤΥΧΩΝ	AA05	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
89	88	07/01/19	4-M4						ΙΧΝΗΛΑΣΙΜΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ ΠΡΟΣΩΠΙΚΟΥ	AE05	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
90	89	07/01/19	5-M5						ΧΕΙΡΟΥΡΑΦΕΣ ΕΠΙΚΕΤΕΣ ΣΕ ΑΝΤΙΡΑΣΤΗΡΙΑ	AA09	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
91	90	07/01/19	6-M6						ΤΕΚΜΗΡΙΩΣΗ ΕΚΠΑΙΔΕΥΣΗΣ ΠΡΟΣΩΠΙΚΟΥ	AA03	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
92	91	07/01/19	7-M7						ΕΝΔΕΙΞΜΑΤΟΣ ΤΟΥ RM ΣΤΟ ΣΔΠ	AA13	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
93	92	07/01/19	8-SD1						ΕΓΚΑΤΑΣΤΑΣΕΙΣ ΠΟΥ ΔΕΝ ΕΛΑΣΦΑΛΙΖΟΥΝ ΤΗΝ ΠΡΟΣΤΑΣΙΑ ΠΡΟΣΩΠΙΚΩΝ ΔΕΔΟΜΕΝΩΝ ΑΙΜΟΔΟΤΩΝ	AA01	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
94	93	07/01/19	9-BC1						ΚΑΤΑΓΡΑΦΗ ΣΙΜΑΤΙΚΟΥ ΒΑΡΟΥΣ ΑΙΜΟΔΟΤΩΝ	ZA01	Συλλογή αίματος	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
95	94	07/01/19	10-BC2						ΜΗ ΤΗΡΗΣΗ SOP ΦΛΕΒΟΚΕΝΤΗΣΗΣ	ZA04	Συλλογή αίματος	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
96	95	07/01/19	11-P1						ΕΣΦΑΛΜΕΝΗ ΕΠΕΡΓΑΣΙΑ ΠΑΡΑΓΩΓΩΝ (ΔΕΥΚΑΦΑΙΡΕΣΗ ΕΚΤΟΣ ΤΩΝ 48 ΩΡΩΝ)	EP03	Επεξεργασία	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
97	96	07/01/19	12-P2,P4						ΕΣΦΑΛΜΕΝΗ ΕΠΕΡΓΑΣΙΑ ΠΑΡΑΓΩΓΩΝ (ΤΕΚΜΗΡΙΩΣΗ ΧΡΩΝΟΥ ΔΕΥΚΑΦΑΙΡΕΣΗΣ)	EP03	Επεξεργασία	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
98	97	07/01/19	13-P3						ΟΡΓΑΝΩΣΙΑΚΕΣ ΕΠΕΡΓΑΣΙΕΣ ΠΑΡΑΓΩΓΟΥ (ΔΕΥΚΑΦΑΙΡΕΣΗ 24 ΩΡΕΣ)	EP03	Επεξεργασία	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
99	98	07/01/19	14-P4						ΕΛΕΓΧΟΣ ΑΝΤΙΣΤΡΩΜΑΤΩΝ ΣΕ ΑΙΜΟΔΟΤΕΣ 1ης ΦΟΡΑΣ	EE03	Εξτάσεις αμοιβούσιων	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
100	99	07/01/19	15-BT2						ΕΦΑΡΜΟΓΗ ΚΑΝΟΝΩΝ GLP	AA13	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
101	100	07/01/19	16-QC1						ΤΕΚΜΗΡΙΩΣΗ ΡΑ ΣΕ ΠΟΙΟΤΙΚΟ ΕΛΕΓΧΟ (ΜΕΤΡΗΣΗ ΑΙΜΟΣΦΑΙΡΙΝΗΣ)	AA05	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
102	101	07/01/19	17-QC2						ΕΛΕΓΧΟΣ ΣΧΕΔΙΟΥ ΠΟΙΟΤΙΚΟΥ ΕΛΕΓΧΟΥ	AA05	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
103	102	07/01/19	18-QC3						ΕΦΑΡΜΟΓΗ SPC	AA05	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
104	103	07/01/19	19-L1						ΕΛΕΓΧΟΣ ΣΤΗ ΣΗΜΑΝΣΗ ΜΟΝΑΔΩΝ (ΑΡΙΘΜΟΣ ΑΙΜΟΔΟΤΗΣ)	AZ02	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	
105	104	07/01/19	20-L2						ΕΣΦΑΛΜΕΝΗ ΠΡΑΚΤΙΚΗ ΣΗΜΑΝΣΗΣ ΜΟΝΑΔΩΝ	AZ02	Άλλα (Αμοιβούσια)	Ανθρώπινο σφάλμα	-	-	ΕΣΟΤΕΡΙΚΗ	ΝΑΙ	EDQM	

**EDQM CAPAs!!**  
with more further down to the next page...

## BARRIERS TO THE PROPOSED CHANGES



PresenterMedia

- Extra efforts were needed to change documents and correct subsequent deviations that were described in the MJV Report

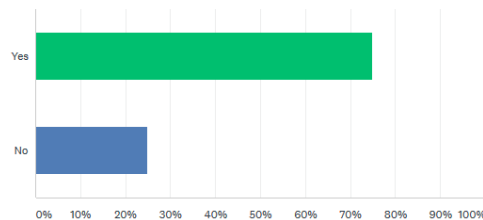


PresenterMedia

- Time constraints present **strong barriers** against prioritizing working systematically in improving quality

### Do you think that you have enough working time to complete the ISO tasks?

Answered: 12 Skipped: 0



ANSWER CHOICES	RESPONSES
Yes	75.00% 9
No	25.00% 3
TOTAL	12

## FACILITATORS OF CHANGE (I)

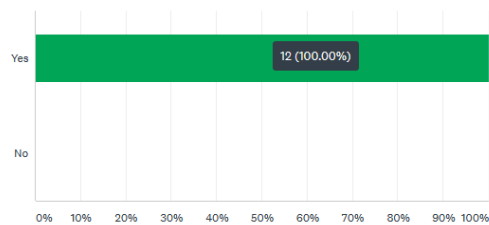
- **Involvement** of all employees
- The positive feeling of **professional pride** is a strong facilitator of change toward improvement of quality:
  - *We want to demonstrate that we are good in what we do. It is a relief to know that our work does not suffer from any critical deviations from high standards [...]*
  - *We felt professional pride; ... we do what we do quite well !"*



## SURVEY QUESTION I

**Do you think that QMS offers the recognition of the quality level of the department both in the hospital and the outer environment?**

Answered: 12 Skipped: 0



ANSWER CHOICES	RESPONSES	
▼ Yes	100.00%	12
▼ No	0.00%	0
TOTAL		12



## CRITICAL ASPECTS OF SUSTAINABILITY

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- The recommended changes and the **acquired knowledge** were substantial (in both number and scope).
- We have put a lot of effort to **retain** and **share** the created knowledge.
- **Sharing** is absolutely crucial as a way of maintaining these changes in the presence of personnel losses or modifications (for example, we faced mid-way in the process a **change** of personnel in a **key member** of our team, under the role of the Quality Manager).

## FACILITATORS TO CHANGE (II)

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- The presence of the **Senior Manager** of the hospital in the final meeting was crucial.
  - She became **aware** that our Department's work is committed to be in conformity with approved standards.
- As a consequence, after the EDQM B-MJV audit, we have had easier access to **resources**, at least for the financial sustainability of QMS (appraisal costs, etc.).

*"It even led to some budget items being approved sooner than they might otherwise have."*



## BENEFICIAL ASPECTS

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- The carry out of the audit resulted, as part of its consequences, in a spill over effect in the hospital

*"they did not necessarily think in the way we do, and it was difficult for them to understand that established structures may need to change for the outcome of quality assurance [...]"*

- We gained **support** and **recognition** for changes concerning **Patient Safety** issues from other interconnected departments of the organization
  - the institution of a PBM office for scheduled surgeries

## NET GAIN

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The audit was of **highest caliber**. We recognize:

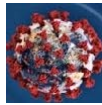
- The profound **changes** that have already occurred or are in the process of still being implemented to our QMS.
- the need of consistent efforts to **sustain** and **share** the acquired knowledge among all the personnel.
- the **awareness** of the hospital's **managerial system** about the necessity to expand QMS in the interconnected departments of the organization

## WHAT COMES NEXT

- We are **still** trying to gradually **reform** our QMS according to the audit recommendations and remarks of the final report
- ✓ drafting of an improved **Quality Master File**
- ✓ establish policies on **Risk Management, Change Control, Quality Control/Statistical process Control and Validation**



- We intend to proceed with the follow up **Blood Mutual Joint Audit (B-MJA)**



## MANY THANKS

10 YEARS OF CO-OPERATION

The **personnel** of GONK-OI AGIOI ANARGYROI would like to thank the auditors' team for their interest in the **B-MJV**, and especially for their sincere and honest **opinions** and **contributions**, which reflect the **importance** they placed in their visit.

