



Cypriot experience with the EDQM B-PTS & B-QM Programmes

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

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Our country

- **Cyprus** is a small country and is **an island**, which add another layer of complexity when it comes to adequacy of blood, emergency situations and procurement of medical devices/material.



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Our Blood Establishment

- Our vision in the Cyprus BE was and is to ensure the adequacy of blood supply as well as the safety and the quality of the transfused blood products.
- **2016** was a year of **great reforms** in the blood services of our country, since it was decided to merge all the small collection and testing units that were dispersed on the island into a **single Blood Establishment**.

Our Country

- **Cyprus** has a long history in **voluntary, non-remunerated blood donation**. With a population of **less than 1 million**, the annual whole blood collections reach the astounding number of **70,000 per year**. This means that we have reached one of the highest percentages globally.
- On the other hand we are faced with **a high percentage of thalassaemia patients** that challenges our supply in blood products.
 - *More than 1 in 10 Cypriots are carriers of its clinically most important form, β thalassaemia, and with currently about 600 β -thalassaemia patients.*
 - *For pairs of carriers each pregnancy has a 25% chance of being affected by the disease*
 - *2014 : Economic crisis*

The Blood community is very strong



B-PTS/B-QM PROGRAMMES – OUR EXPERIENCE

10 YEARS OF
CO-OPERATION

B-PTS programme:

- Since 2015: regular participation in EDQM B-PTS programme
- Today: regular participation & recently joined the NAT programme following recent implementation of **NAT testing** – **Our participation in the NAT programme was crucial to make sure that results from our newly implemented method were reliable.**

B-QM programme: 2 visits

- 1 B-TV in **2012** (former Director)
- 1 B-MJV in **2016**
- **Planned 1 B-MJV in 2020 but COVID-19**

B-QM programme: our needs in 2016

The **merge** of all the small collection and testing units into a single BE inevitably required an independent assessment of this endeavour and thus we applied in 2016 for participation in the audit programme of the B-MJV of EDQM.

Merge triggered some challenges:

- Where to locate the centralisation of testing and processing on a island?
- how to secure the cold chain? Especially during the summer

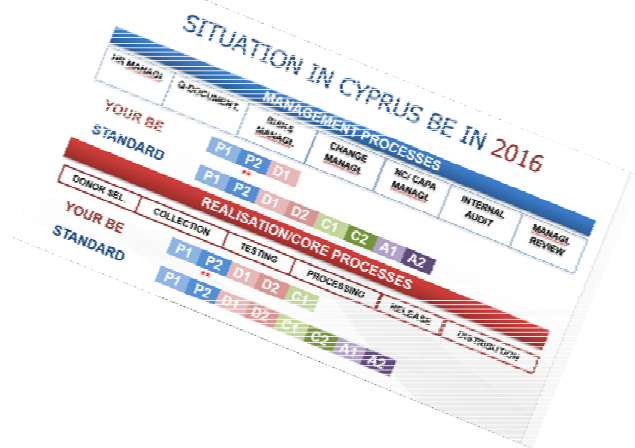
We needed **advice and support from peers**

‘Collecting and processing blood on an island and even more during the summer time is not the same as in continental countries’

The Journey

- 3 days including auditing mobile site in the middle of the island
- To help us understanding and help us to [set the directions](#)

>>> > **Quality management barometer** that enables to show the progress between the 1st & 2nd visit



B-MJV: what we learn, what was the impact?

- The professional yet friendly approaches of the inspectors lead to a **series of improvements in our service**. Their recommendations were the **building blocks** of our quality assurance programme which ultimately benefited the transfused patients.
- We implemented a **successful Quality Assurance programme** in the BE, including **Quality Manual, auditing programme and preventive and corrective actions**.
- The main changes were improvements concerning: **risk management, internal audits, SOPs, cold chain and traceability**.
- It also included provision of **training on needed topics (e.g. change control)**

‘By assessing the goals set by the programme, the visit by the experts was a very positive experience as their comments and expertise were an invaluable asset to our recently implemented quality assurance programme’.

B-MJV: what we learn, what was the impact?

- We managed to improve the work done by BE, achieving high standards and improving the **therapeutic value of blood transfusion**.
- It also created also a **team spirit & cohesion** within our team to pursue our efforts

We highly recommend the participation in the B-QM programmes of EDQM. Our country has already put in a new application and we **anxiously** wait, this time for our participation in the Blood Mutual Joint Audits (B-MJAs) programme.