CH. SRIDHAR

MANAGER – MICROBIOLOGY
ICHOR BIOLOGICS PVT. LTD.
HYDERABAD.

ICHOR BIOLOGICS

- Ichor is a specialty plasma derived biopharmaceuticals company committed to innovate, develop and commercialize high-quality plasma derivatives to save lives and enhance the quality of life for the people.
- Ichor has a state-of-the-art cGMP/WHO GMP compliant plasma fractionation facility
- Location - Genome valley , Hyderabad.
- Has end-to-end chromatography-based process for production of plasma derivative
- High quality plasma derivatives manufactured in the facility are being marketed since 2013

Products –

- Human Albumin (HEMALB™)
- Human Normal Immunoglobulin (IMMUGLO™ / (IGAMMA))
- Human Coagulation Factor IX (CLOTNINE™)

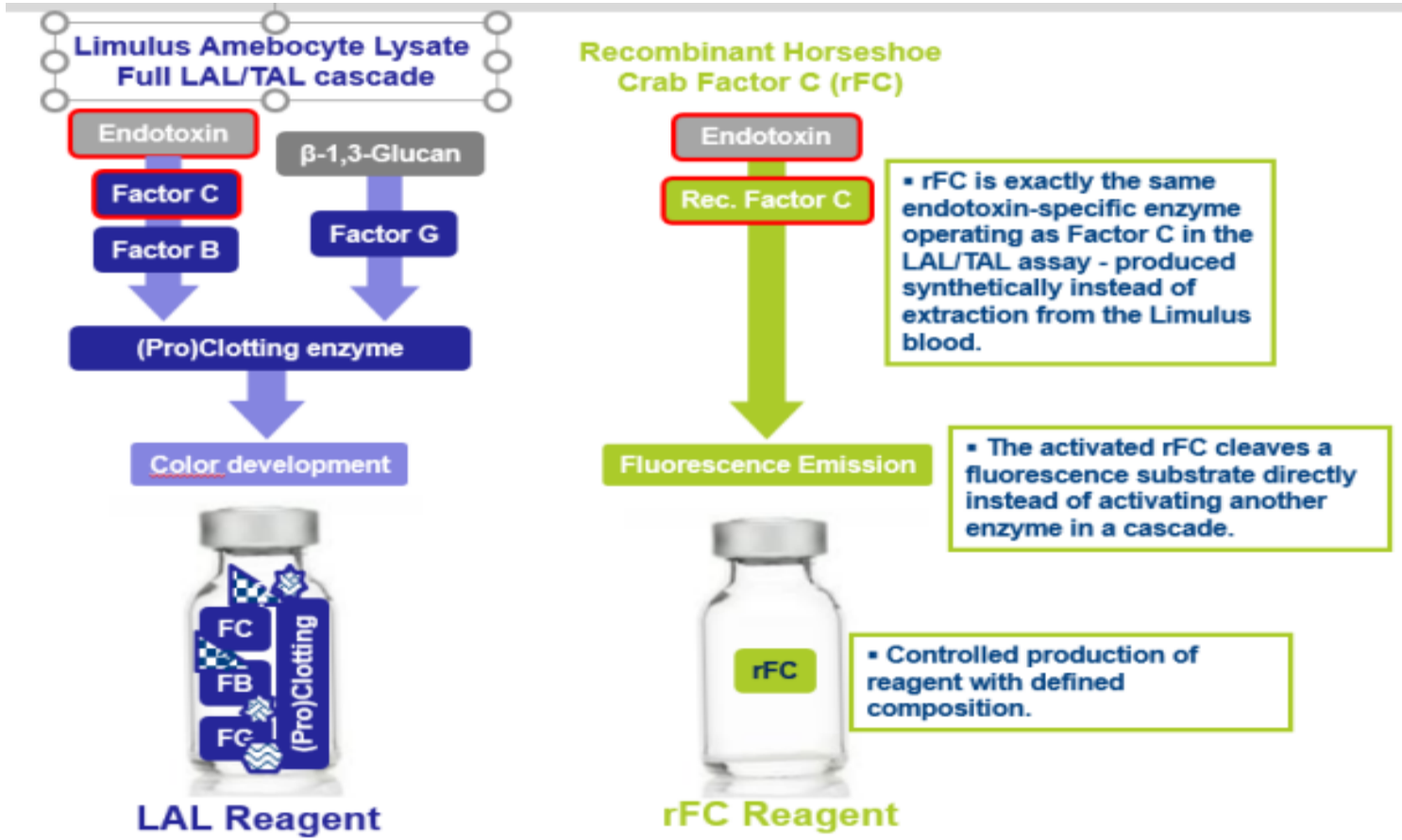
ALTERNATE METHOD TO GEL-CLOT

- Various trials performed using the Gel clot, Kinetic technologies
- Information regarding rFC technology from solution provider
- Literature explained about the repeatability and compatibility.
- Decision was made to get a trial with this technology.

Assessment & Trial study

- The solution is great and meets our expectation.
- Difficult products like Human albumin, immunoglobulin and Human fibrinogen were tested on the system
- Results found as per the regulatory expectations such as 50 to 200 % recovery compared to LAL reagent .
- The results were satisfactory. The assessment was done following various steps, and products were tested for multiple batches - repeatability shown in results.

GEL-CLOT vs rFC



Regulatory View on Recombinant Factor C (rFC)

- Recombinant horseshoe crab Factor C (rFC) is an exact synthetic copy of the endotoxin sensitive enzyme naturally harbored by the blood of horseshoe crabs.
- Compared with Limulus amebocyte lysate (LAL) methods, endotoxin detection assays based on rFC offer specificity, flexibility, lot-to-lot consistency and, importantly, a sustainable, animal-saving and secure source.
- rFC tests are available as fluorescence end-point assays in 96-well microplate format and are validated in the same way as conventional methods according to pharmacopoeia bacterial endotoxin testing chapters.
- The US FDA recently approved product release using rFC for Eli Lilly and defines the requirements for rFC in Guidance for Industry Pyrogen and Endotoxins Testing.
- The European Pharmacopoeia includes rFC as an alternative method in Ph. Eur. Chapter 5.1.10 and published the world's first draft general chapter for rFC, Ph. Eur. 2.6.32 in December 2018.
- The Japanese Pharmaceutical and Medical Device Agency has so far published two collaborative studies demonstrating equivalence between rFC and LAL assays.

Transition from LAL to rFC

We are looking forward positively to move to this technology as the results are very satisfactory. It is specific and results are repeatable. Also, the technology is recognised by various regulatory bodies now. It will be an easy transition, and solution will be helpful for us.

THANK YOU