



*Knowledge, Skills and Passion.*

**FMAP – Flexible  
Modular  
Automation  
Platform**

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# Background/Introduction

Cell and gene therapy is in its early stage of commercialization using low level of automation and large number of laboratory equipment, each with its unique interface.

Because of this, pharma companies are facing the following challenges:

- how to provide patient safety by controlling variabilities of CQAs
- how to shorten process time
- how to efficiently control and document all process steps
- how to properly train operators
- how to reduce or mitigate risks of manual steps in the process
- how to reduce manufacturing costs

**FMAP** was developed to address all these challenges



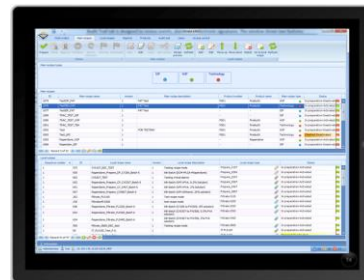


# What is FMAP?

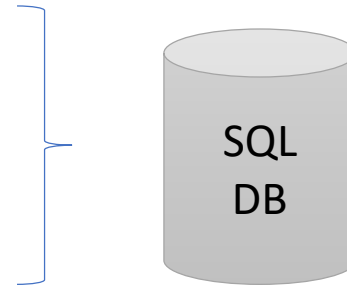
- FMAP is **advanced process monitoring, control and data management** platform
- It **integrates** process and analytical equipment into a single platform allowing user to run the whole process through **unified and simple interface**
- It is a permanent solution for flexible processes



PEM



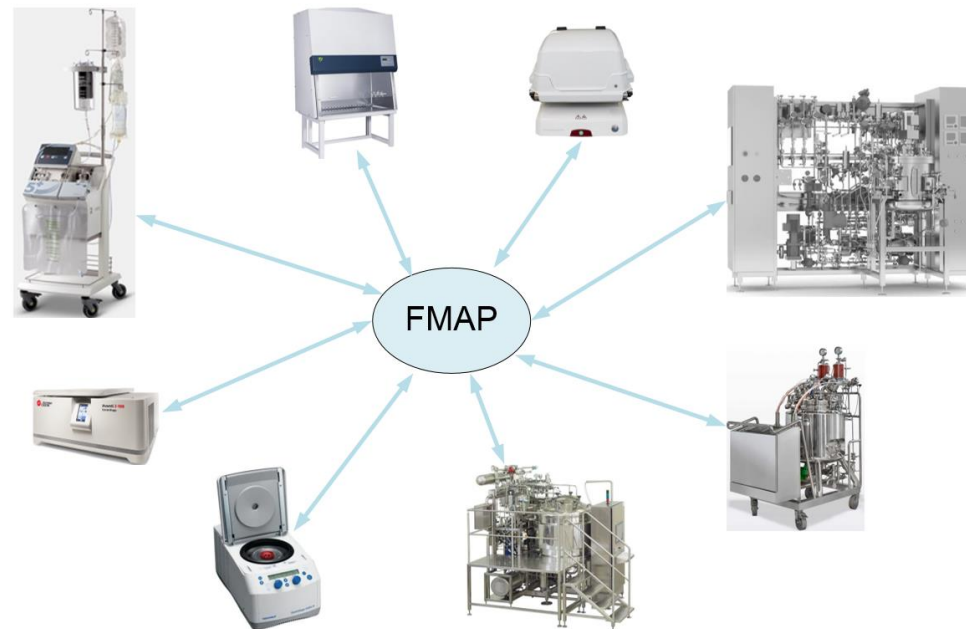
PDBM





# FMAP Purpose

FMAP was designed to be the heart of typical biomanufacturing process control. It represents **robust** and **cost effective** solution for flexible and modular production processes.





# FMAP Advantages

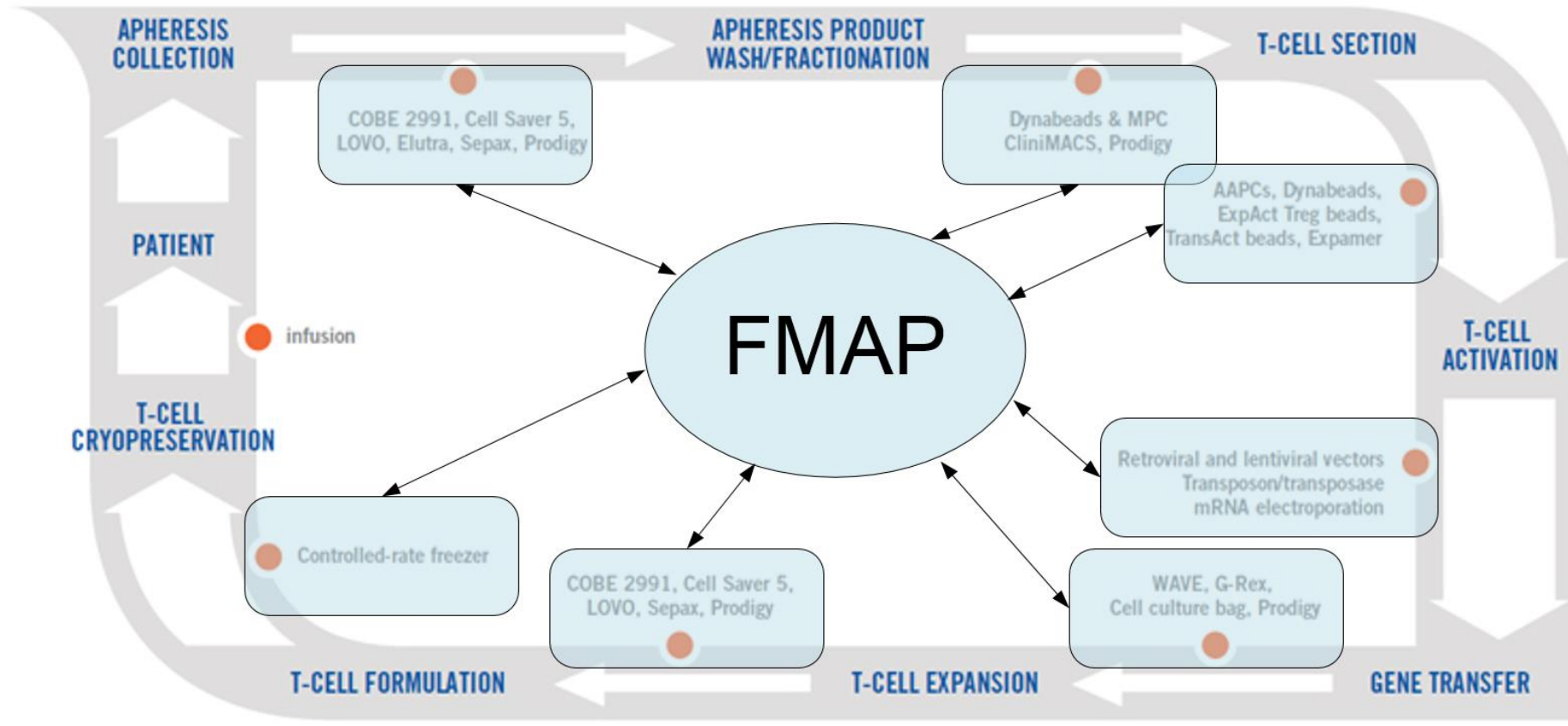
- FMAP helps to **mitigate risks** associated with CGT production
- It combines powerful **recipe editor, audit trail, reporting module** and various add on modules like PAT.
- It represents a single stop for **efficient process control**.
- FMAP part of the RIM – Regulatory Information Management
- FMAP **unifies data** from different process equipment
- FMAP **simplifies** process control
- FMAP is designed for **modular systems**





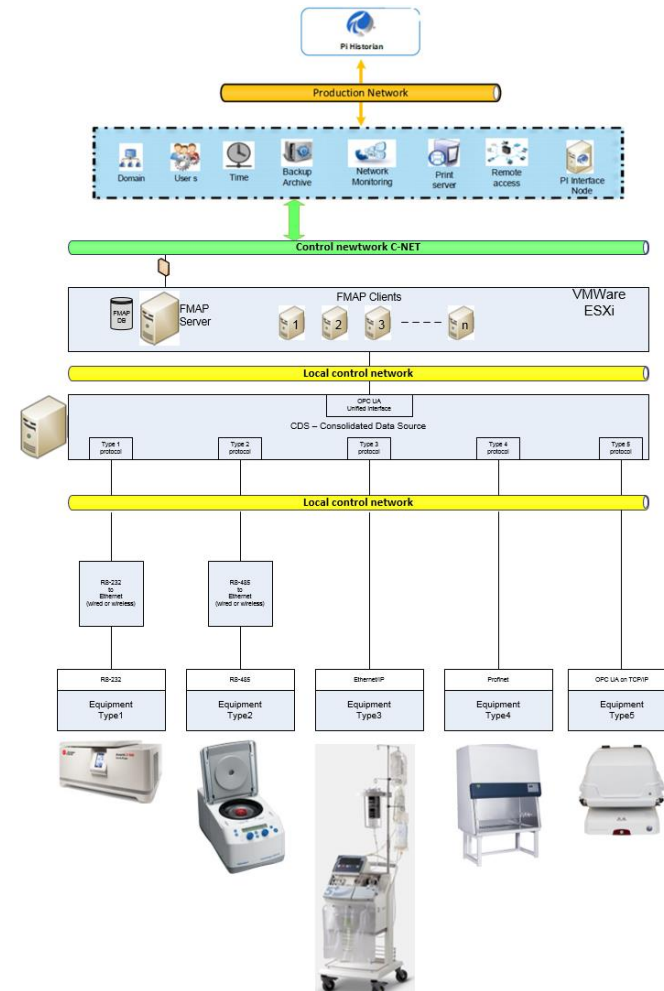
# FMAP – The Heart of Your CGT Process

## CELL GENE THERAPIES





# FMAP architecture





# Recipe Dashboard

Process Execution Manager

User: None Client ID: 22256 Date: 28.01.2019 Time: 10:33:23

Patient 1 CAR-T A Full	Patient 2 CAR-T A Stop B Full	Patient 3 CAR-T A In G Full	Patient 4 CAR-T B Full	Patient 5 CAR-T B Full	Patient 6 CAR-T B Read only	Patient 7 CAR-T B Read only
Patient 8 CAR-T B Full	Patient 9 CAR-T C Read only	Patient 10 CAR-T C Read only	Patient 11 CAR-T C Read only	Patient 12 CAR-T A Read only	Patient 13 CAR-T B Read only	Patient 14 CAR-T A Read only
Patient 15 CAR-T B Full	Patient 16 CAR-T B Full	Patient 17 CAR-T B Full	Patient 18 CAR-T B Full	Patient 19 CAR-T B Full	Patient 20 CAR-T B Full	Patient 21 CAR-T B Full
Patient 22 CAR-T B Full	Patient 23 CAR-T B Full	Patient 24 CAR-T B Full	Patient 25 CAR-T B Full	Patient 26 CAR-T B Full	Patient 27 CAR-T B Full	Patient 28 CAR-T B Full
Patient 29 CAR-T B Full	Patient 30 CAR-T B Full	Patient 31 CAR-T B Full	Patient 32 CAR-T B Full	Patient 33 CAR-T B Full	Patient 34 CAR-T B Full	Patient 35 CAR-T B Full

SYSTEM TOOLS PDBM

Patient 2 Unit ID: 1647 Recipe: CAR-T A Access mode: Full Date: 28.01.2019  
User: Philippe Prause Client ID: 22256 Batch: 5567754 Time: 10:33:23

```
graph TD; Start[Check start conditions] --> B0[Object: B0  
Operation: Pressure  
(BestOP, DoseAuto,  
DoseManual)]; Start --> C0[Object: C0  
Operation: Pressure  
(BestOP, DoseAuto,  
DoseManual)]; Start --> A0[Object: A0  
Operation: Pressure  
(BestOP, DoseAuto,  
DoseManual)]; B0 --> B0C1[Object: B0-C1  
Operation: Filtrate B0->FL->C1]; C0 --> C0C1[Object: C0-C1  
Operation: Filtrate C0->FL->C1]; B0C1 --> Standalone[Object: stand-alone container  
Operation: Prepare API]; C0C1 --> Standalone; A0 --> Standalone;
```

START HOLD RESUME ABORT SYSTEM CLOSE







# Equipment Dashboard

Process Execution Manager

User: None Client ID: 22256 Date: 28.01.2019 Time: 10:33:23

BR1 Kymriah 1	BR2 Kymriah 2	BR3 Kymriah 3	BR4 Kymriah 4	BR5 Kymriah 5	BR6 Kymriah 6	BR7 Kymriah 7
BR8 Kymriah 8	BR9 Kymriah 9	BR10 Kymriah 10	BR11 Kymriah 11	BR12 Kymriah 12	BR13 Kymriah 13	BR14 Kymriah 14
BR15 Kymriah 15	BR16 Kymriah 16	BR17 Kymriah 17	BR18 Kymriah 18	BR19 Kymriah 19	BR20 Kymriah 20	BR21 Kymriah 21
BR22 Kymriah 22	BR23 Kymriah 23	BR24 Kymriah 24	BR25 Kymriah 25	BR26 Kymriah 26	BR27 Kymriah 27	BR28 Kymriah 28
BR29 Kymriah 29	BR30 Kymriah 30	BR31 Kymriah 31	BR32 Kymriah 32	BR33 Kymriah 33	BR34 Kymriah 34	BR35 Kymriah 35

SYSTEM TOOLS PDBM

Position number: 3 Unit ID: 4456 Recipe: CAR-T A Access mode: Full Date: 28.01.2019

User: Philippe Prause Client ID: 22256 Batch: 5567754 Time: 10:33:23

	SP	CV	Low Alarm	High Alarm	UM	Refresh Period [s]	Controlled by
DO	40	39	-5	+5	%	120	O2
pH	7.00	7.01	-0.10	+0.10	-	120	CO2
Temp	36.0	35.8	-10.0	+10.0	°C		
Media control	10.00	10.03	-0.10	+0.10	kg		
Gas control	1.00	0.99	-0.05	+0.05	l/min		
O2	21.0	20.4	-2.0	+2.0	%		
CO2	0.0	0.1	-1.0	+1.0	%		
Pump1	200.0	0.1	-10.0	+10.0	rpm		Acid
Pump2	1.0	0.1	-1.0	+1.0	ml/min		Base

Current state: Idle Weight: 0.34 kg

Rocking Speed: 25 rpm  
Angle: 4 °  
Sampling pause: 1 min  
Sampling angle: 0 °

START HOLD RESUME ABORT PAIR SYSTEM CLOSE





# About TRAC

<b><u>1992</u></b> since	<b><u>28+</u></b> countries	<b><u>500+</u></b> finished projects
over 25 years experiences in the pharmaceutical industry	global presence	successful complex and high- tech projects in different areas:

[www.trac.si](http://www.trac.si)

