
The tableting process behind the pill

IMAGO – a galenic software

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Who is IMA



Founded in 1961, IMA is world leader in the design and manufacture of equipment for the processing and packaging of drugs, cosmetics, tea, coffee and foods. Actual turnover is over 1.5 Billion €.

IMA Active, one of the three Pharma Divisions, is the ideal partner for each solid dose processing phase.

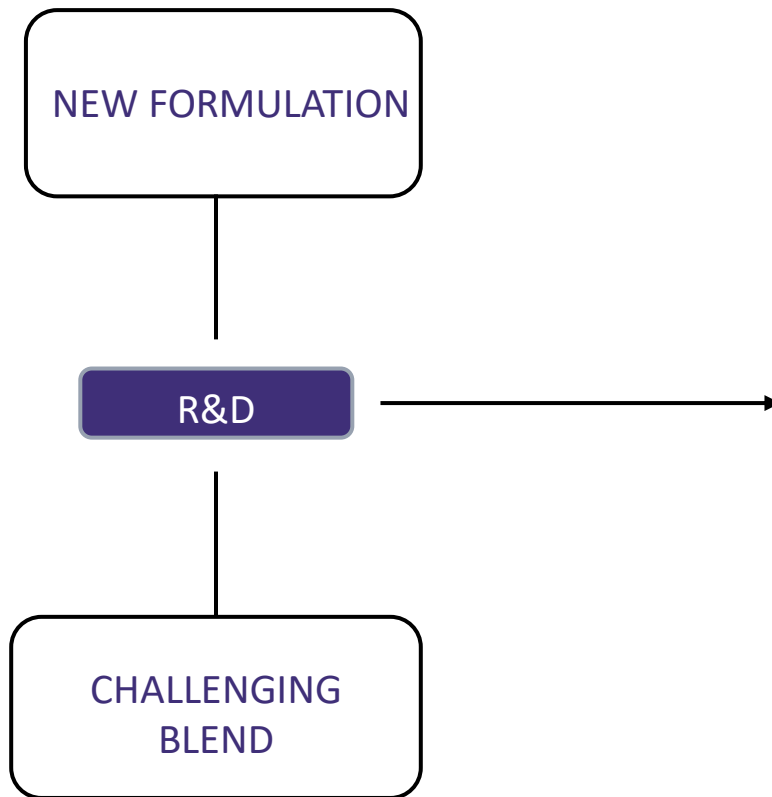
The **IMA Active** solutions are based on individual product lines, but also capable of sharing and cultivating such knowledge within a team.

IMA Active not only provides a vast selection of integrated equipment but also a host of tailored solutions for specific installations.

After years of study and observation **IMA Active** has also taken steps towards **Continuous Manufacturing** with the US company either truly innovative either empowering batch technologies with the IMA Active Research and Development team.

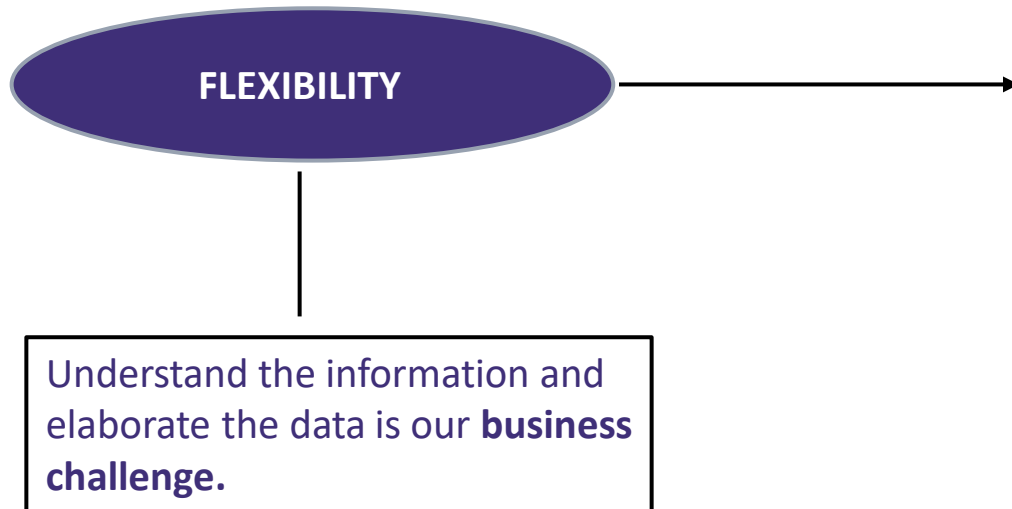


From a scientific point of view



- Detection and analysis of the variables of the compression process.
- Analysis of the powder's behaviour: stages of development of a formulation, changes within the formulation in order to assess the impact on the process.
- Study of the influence of process parameters on the formulation and tablets.
- Simulation of product behaviour from pilot plants to production machines: scale-up.

From a scientific point of view



- A system completely integrate whose access is able through a laptop.
- Ready-to-use system with all the analysis instrument (no excel).
- Possibility of customization in case of particular variables to be explored.

Case study

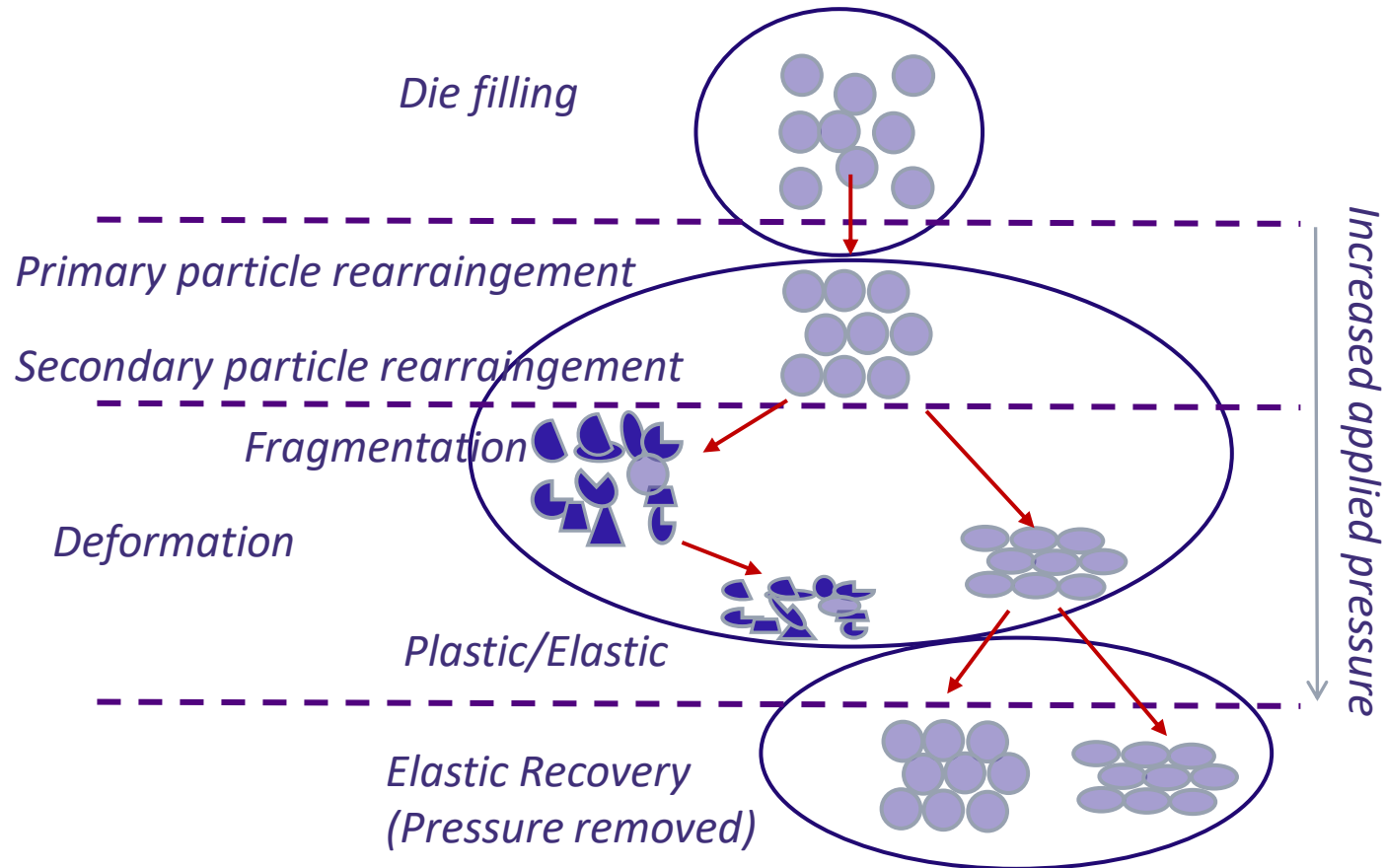
PLASTIC FORMULATION		
Compounds	%	kg
Tablettose® 80	66.33	16.583
Vivapur® 102	33.17	8.293
Mg Stearate	0.5	0.125

ELASTIC FORMULATION		
Compounds	%	kg
Starch® 1500	88.55	22.388
Vivapur® 102	9.95	2.488
Aerosil® 200 Pharma	0.25	0.063
Mg Stearate	0.25	0.063

Comparison between two formulations:

- Curve force vs time.
- Tablets characteristics.
- Tabletability, compactibility and compressibility.

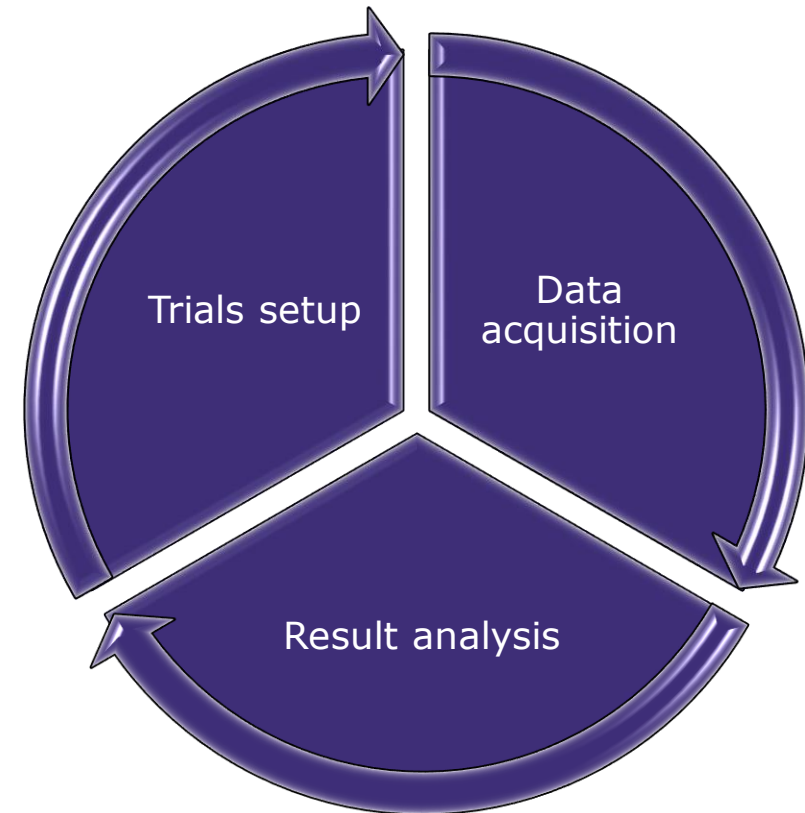
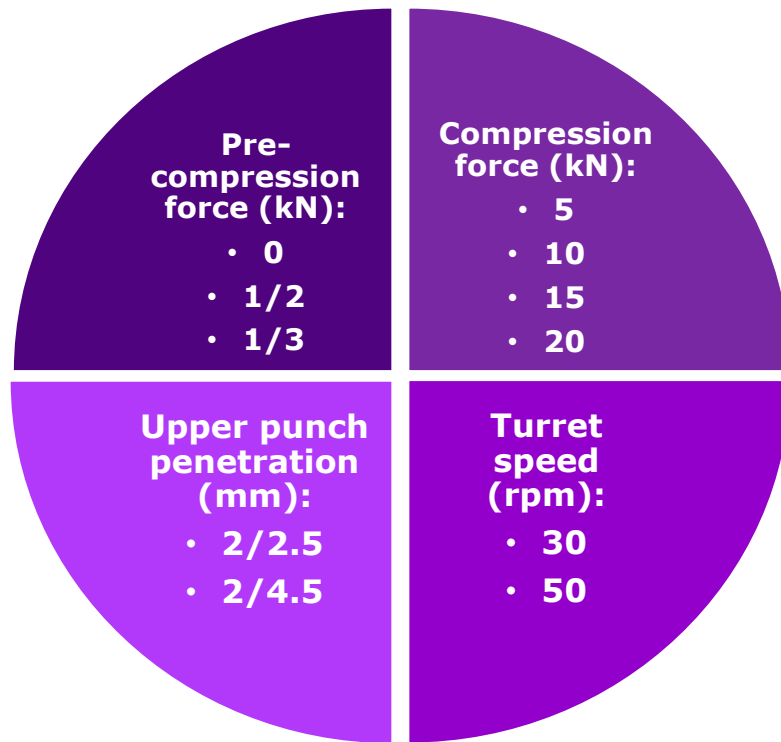
Tableting



How can it be translated in results?

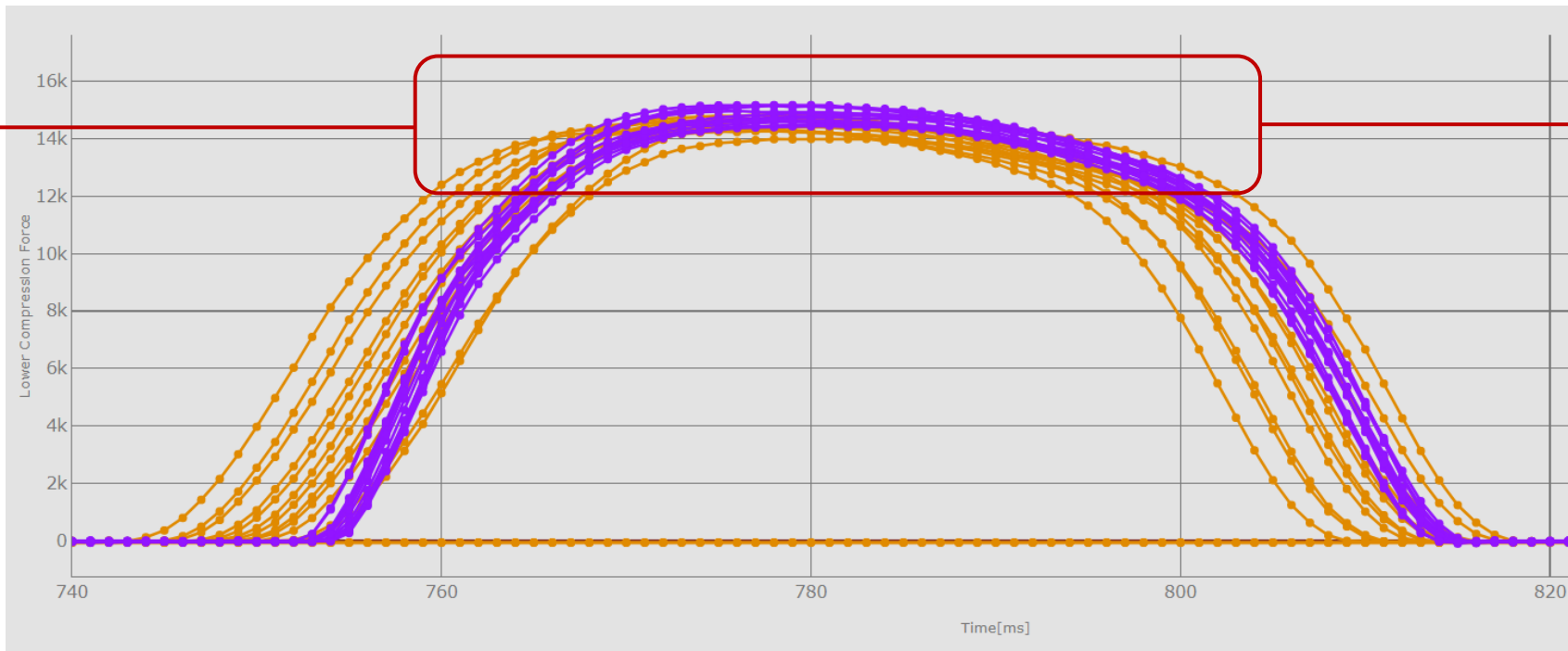
- Typical peak force vs time.
- Tablets features: lower thickness and higher tablet strength.
- Enhanced tableability, compressibility and compactibility: higher tensile strength as well as solid fraction.

Case study



Results: curve forces vs time

Peak shape gives information about powder behavior over tableting phase



ELASTIC:
Visco-elastic properties increase the force exerted by the powder bed under tableting generating a more elongated peak.

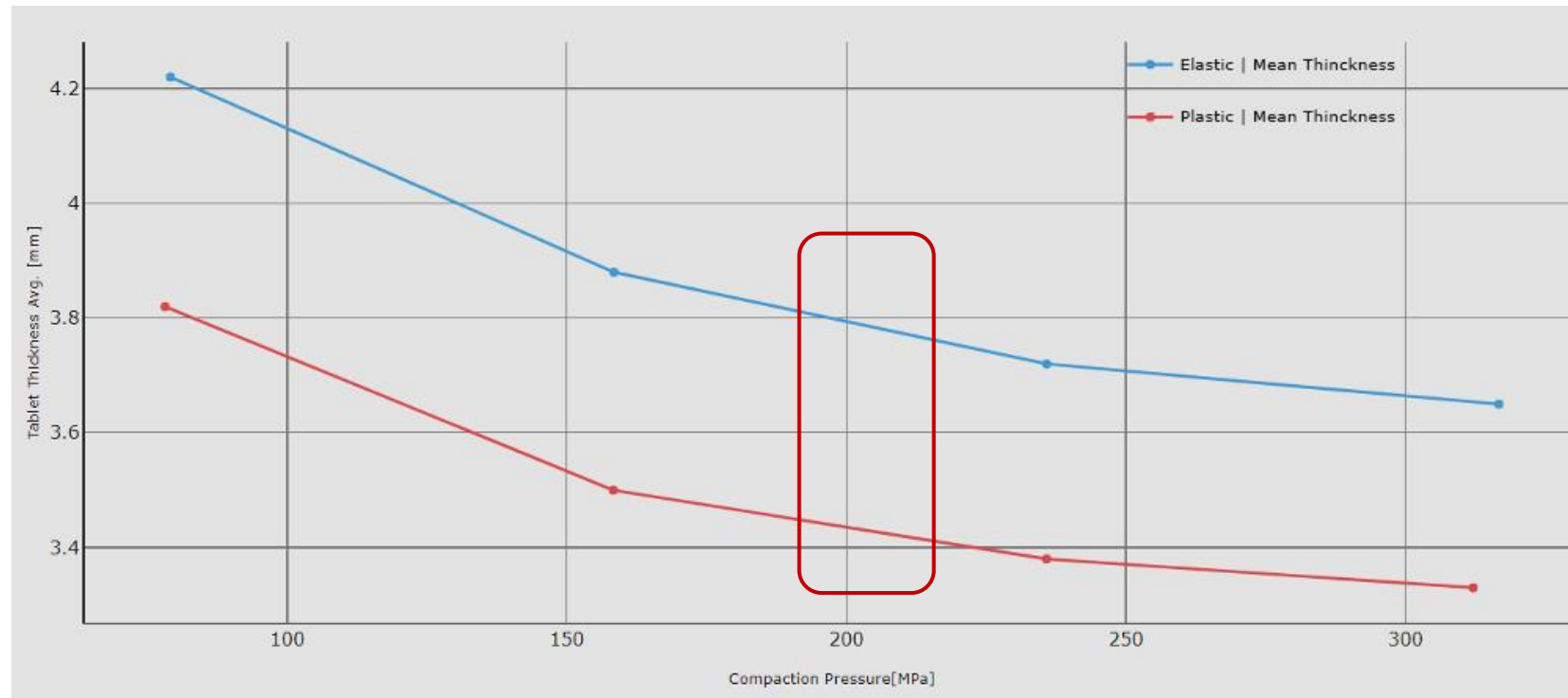
PLASTIC:

- Tighter bonds
- Less porosity

Results: thickness and hardness

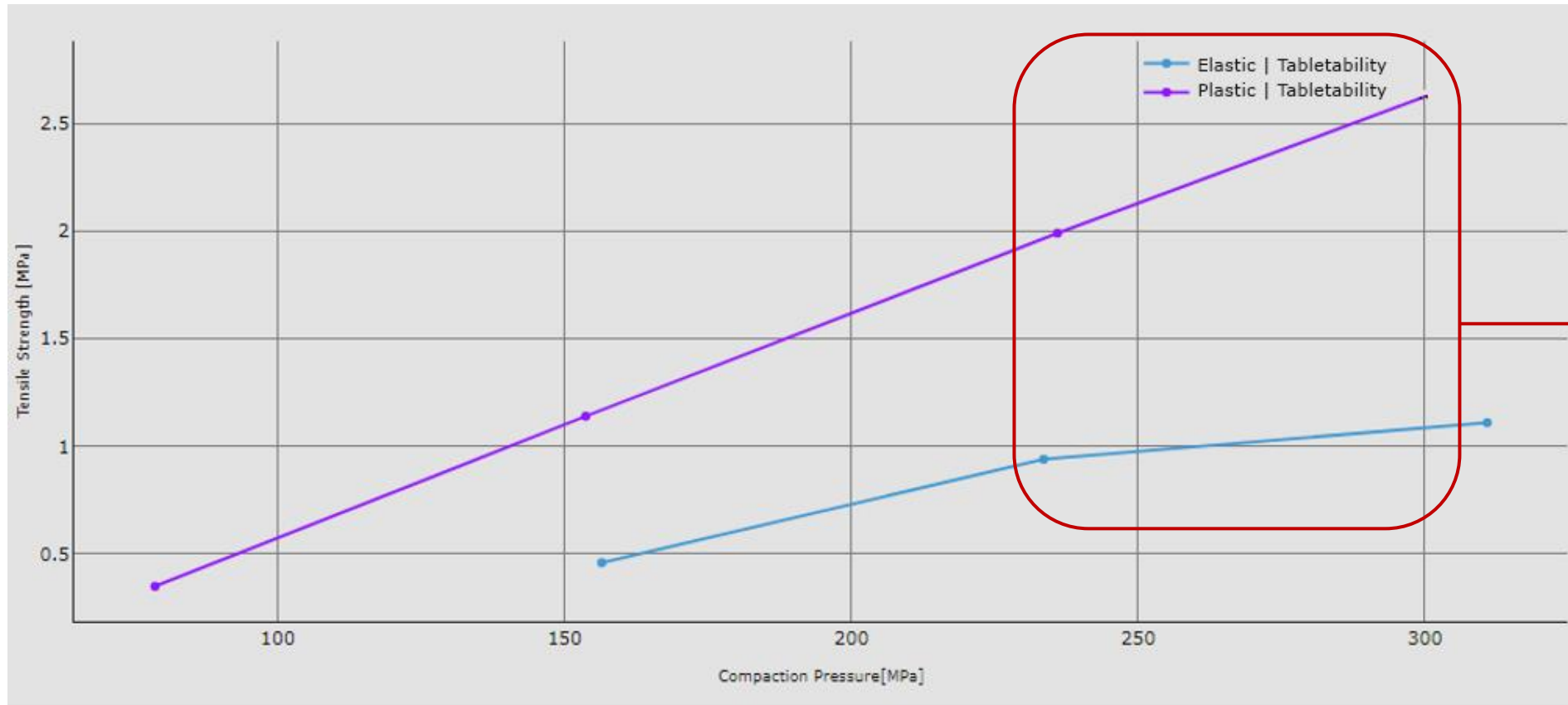
At same tablet press parameters and tablets characteristics:

- Thickness is less for plastic formulation due to the tighter bonds that the compression phase is generating.
- Thickness increases for elastic blends also because of inner tablets relaxation.



Results: tableability (hardness)

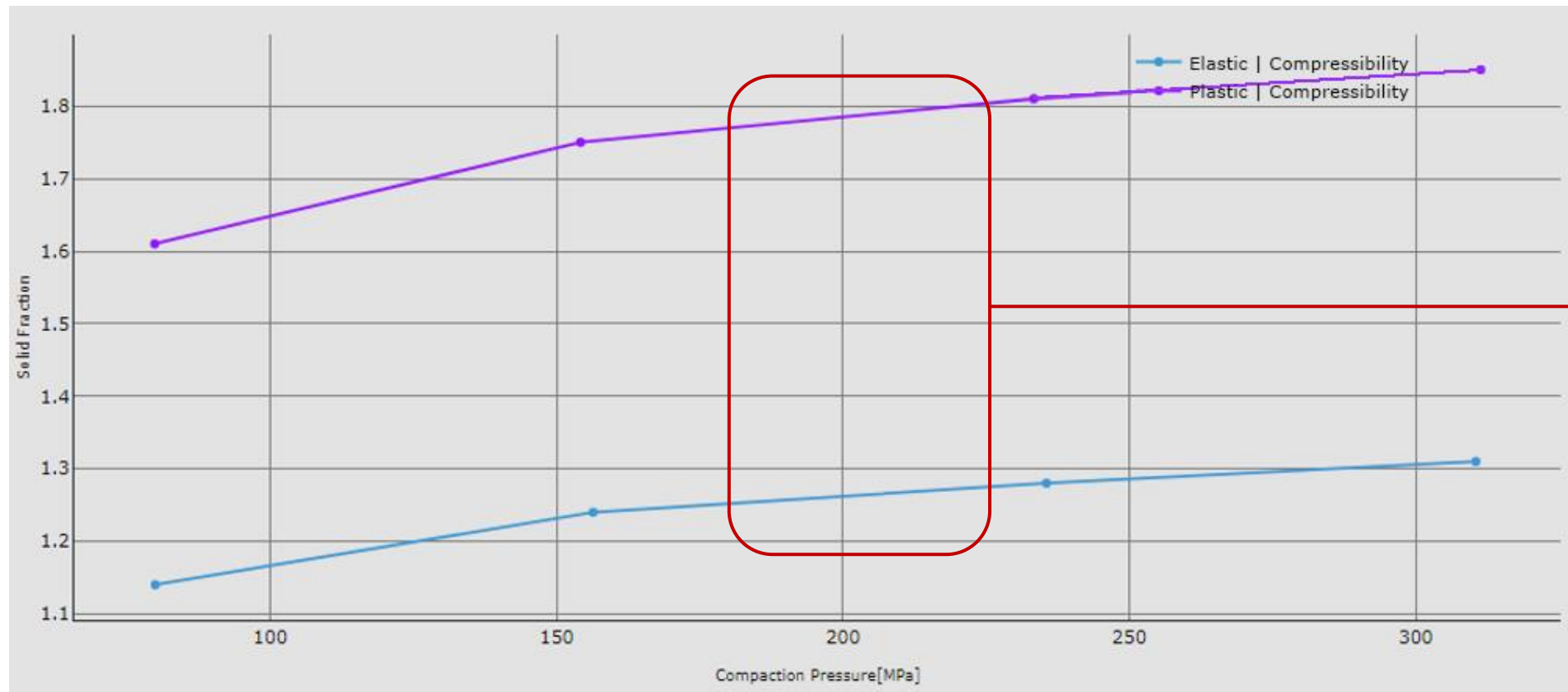
It represents the powder tendency to be transformed into tablets.



Particles breaking point definitely higher due to increased bond-ability

Results: compressibility

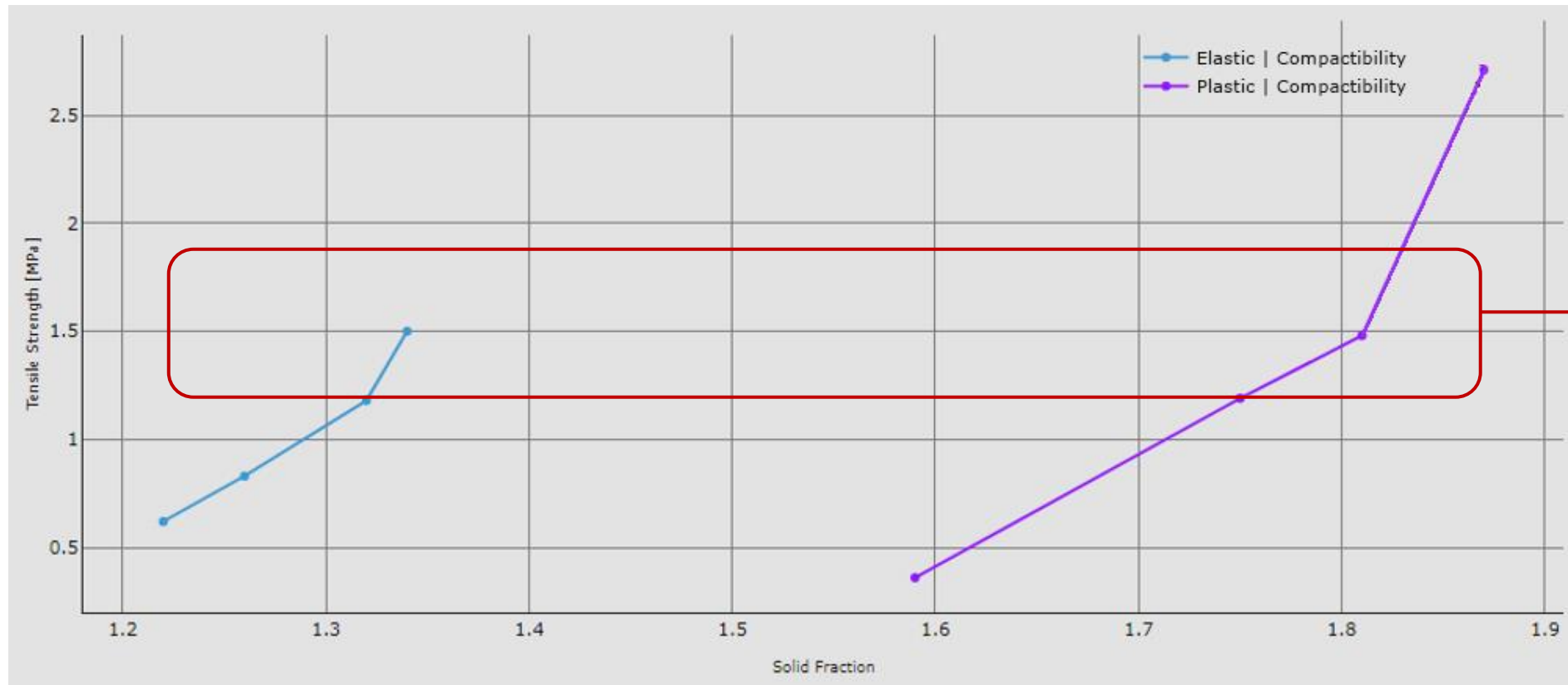
It represents the powder tendency to remain compacted under an applied force.



Particles inner tendency to recover their original position

Results: compactability

It represents the powder tendency to reduce its volume if compressed.



- The relaxation *phenomena* affect volume decreasing.
- Tighter bonds improves reduction of volume.

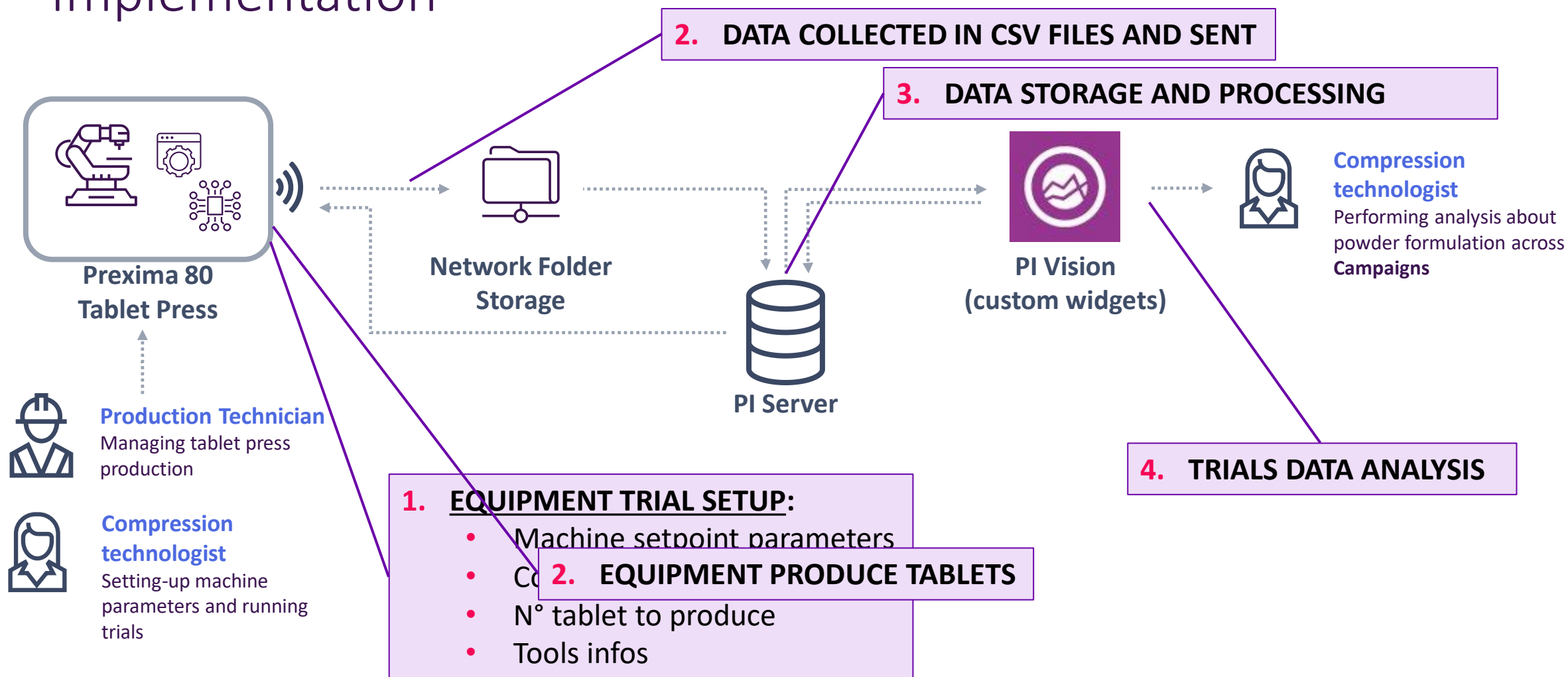
The challenge



Integrate entire process in one application running on a «real tablet press process» machine.

- Real process data
- Simple to use: data ready to use, organized in the right way
- No overhead to manage data (cleaning, aggregation, ...)

Implementation



Technical solutions – Data collecting

- Collect data from machines:
 - Acquire data from load cells sensors in the tableting process (precompression phase, compression phase, tablet expulsion phase).
 - **Many data every millisecond!!**

- A scalable and reliable solution: **PI UFL Connector (Universal File Loader)**
 - No data lost
 - Acquire a huge amount of data
 - Ease to configure
 - Ease to extend data model

Technical solutions - Modelling

- Quick and easy modelling: **Asset Framework**
- Group trials into hierarchical model to let user find what he want in easy way.

PREXIMA 300.KC.1018

Filter

Campaign

Compound1Name	Starch 1500
Compound2Name	Vivepar 102
Compound3Name	Aerol 200 pharma
Compound4Name	NaSt
Compound5Name	NA
Compound6Name	NA
Compound7Name	NA
Compound8Name	NA
Compound9Name	NA
Compound10Name	NA
Compound11Name	NA
Compound12Name	NA
Compound13Name	NA
Compound14Name	NA
Compound15Name	NA
Compound16Name	NA
Compound17Name	NA
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Compound90Name	NA
Compound91Name	NA
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Compound93Name	NA
Compound94Name	NA
Compound95Name	NA
Compound96Name	NA
Compound97Name	NA
Compound98Name	NA
Compound99Name	NA
Compound100Name	NA

Formulation

IMA ACTIVE | IMAGO

IMA_GALENIC/Galenic 21/09/2020 12:07 pm

Trials selection

02/02/2020 00:00:00

21/09/2020 00:00:00

MONDELEZ

OMEPRAZOLO

placebo meggle

Polaris

F10

40rpm-I

Tablet & Tooling

Force trend

X-Y Analysis

Trend

Polaris	F10	40rpm-I	27/02/20 15:48:40	27/02/20 15:48:43
Polaris	F10	40rpm-II	27/02/20 15:51:28	27/02/20 15:51:31
Polaris	F10	40rpm-III	27/02/20 15:54:51	27/02/20 15:54:54
Polaris	F10	40rpm-IV	27/02/20 15:56:45	27/02/20 15:56:48

Formulation

BulkDensity	mg/mL	0.5
CarrIndex	%	16.66
Compound10Name		No Data
Compound10Percentage		No Data
Compound1Name		flowlac
Compound1Percentage	%	59.5

Technical solutions - Interoperability

- Guided process and data flow integration: **PI SQL Client and RTQP Engine.**

The screenshot displays a web application interface for creating a galenic test. The interface is titled "Anagraphic new galenic test" and is divided into three main sections for data entry:

- Campaign name:** A dropdown menu showing "Placebo BASF" with a plus sign to the right.
- Campaign code:** A text input field containing "001".
- Formulation name:** A dropdown menu showing "FINAL FORMULATION" with a plus sign to the right.
- Formulation code:** A text input field containing "001A".
- Test name:** A text input field containing "test6".

At the bottom right of the form, there are two buttons: "Reset all" and "Create test".

Three purple circles are drawn on the left side of the form, with arrows pointing to the "Campaign name", "Formulation name", and "Test name" dropdown menus. This indicates the data flow from these fields to the "Create test" button.

Technical solutions – Enhanced functionality

- Quick and easy modelling: **Asset Framework**
 - Complex analytics from machine raw data.
 - Possibility to input and store missing data during data collecting (*tablets characteristics*).

The screenshot displays the IMAGO software interface, which is used for tablet characterization. The interface is divided into several sections:

- Header:** IMA ACTIVE | IMAGO on the left, and IMA_GALENIC/Galenic | 21/09/2020 12:14 pm on the right.
- Navigation:** Trials selection, Tablet & Tooling (highlighted in teal), Force trend, and X-Y Analysis.
- Tablet Selection:** A list of tablets with columns for Polaris, F10, and 40rpm-I/II. A purple arrow points from this section to the data table.
- Data Table:** A table with columns for Dwell time [ms], Mean End Weight [mg], Mean Initial Weight [mg], Mean True Density [g/mL], and Mean Wall Height [mm]. The table is divided into sub-sections for Weight [mg], Thickness [mm], Diameter [mm], and Hardness [N].
- Summary Table:** A table on the left side of the main data table, listing various characteristics such as Calc, Mean End Weight, Mean Initial Weight, Mean True Density, Mean Wall Height, Tablet surface area, Friability, Porosity, Solid Fraction, and Tensile Strength.

	Dwell time [ms]	Mean End Weight [mg]	Mean Initial Weight [mg]	Mean True Density [g/mL]	Mean Wall Height [mm]				
	0	258	258.5	0.96	7.39				
Weight [mg]		Thickness [mm]		Diameter [mm]		Hardness [N]			
Mean: 3714.53	σ%: 0.32	Mean: 7.391	σ%: 0.165	Mean: 25	σ%: 0	Mean: 46.6	σ%: 4.912		
Tablet005		7.38		25		49			
Tablet006		7.38		25		46			
Tablet007		7.42		25		47			
Tablet008		7.38		25		44			
Tablet009		7.38		25		46			
Tablet010		7.39		25		49			
Tablet011		7.39		25		44			
Tablet012		3724.9		7.4		25		48	
Tablet013		3707.3		7.4		25		50	
Tablet014		3712.6		7.39		25		43	

Technical solutions - UX

- Data flow integration: **PI Vision**
 - Front end with same family feeling of machine HMI.

The screenshot displays the IMAGO software interface. At the top, the header includes the IMA ACTIVE logo, the name 'IMAGO', and a user profile for 'IMA_GALENIC/Galenic' with the date '21/09/2020 12:07 pm'. Below the header, there are four main navigation tabs: 'Trials selection' (highlighted in teal), 'Tablet & Tooling', 'Force trend', and 'X-Y Analysis'. Under the 'Trials selection' tab, there is a search bar and a list of trial categories: 'MONDELEZ', 'OMEPRAZOLO', 'placebo meggie', 'Polaris', 'F10', and '40rpm-I'. To the right of the search bar is a 'Trend' button. Below the trial list is a table with the following data:

Polaris	F10	40rpm-I	27/02/20 15:48:40	27/02/20 15:48:43
Polaris	F10	40rpm-II	27/02/20 15:51:28	27/02/20 15:51:31
Polaris	F10	40rpm-III	27/02/20 15:54:51	27/02/20 15:54:54
Polaris	F10	40rpm-IV	27/02/20 15:56:45	27/02/20 15:56:48

Below the trend table is a 'Formulation' table with the following data:

Formulation			
BulkDensity		mg/mL	0.5
CarrIndex		%	16.66
Compound10Name			No Data
Compound10Percentage			No Data
Compound1Name			flowlac
Compound1Percentage		%	59.5

Technical solutions - UX

- All at right place for analysis:
 - Intuitive e guided process
 - Compare data of different trials

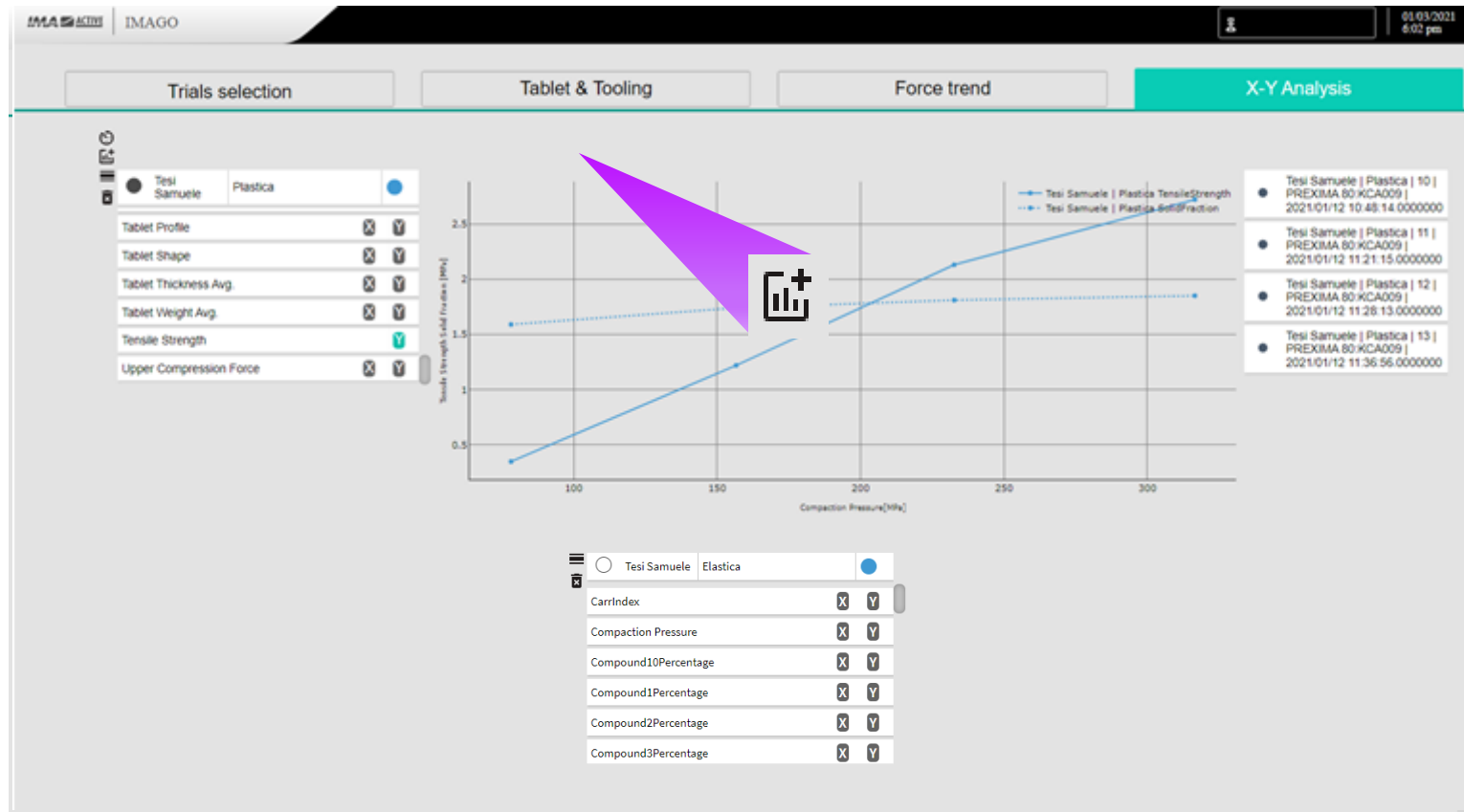
The screenshot displays the IMA ACTIVE IMAGO software interface. At the top, the header includes the IMA ACTIVE logo, the name 'IMAGO', and user information 'IMA_GALENIC(Galenic)' with a timestamp '21/09/2020 12:07 pm'. Below the header, a navigation bar features four steps: 'Trials selection' (highlighted in teal), 'Tablet & Tooling', 'Force trend', and 'X-Y Analysis', connected by blue arrows. The main workspace is divided into several sections. On the left, there are date range selectors for '02/02/2020 00:00:00' to '21/09/2020 00:00:00' and a search bar. Below these are filter buttons for 'MONDELEZ', 'OMEPRAZOLO', 'placebo meglee', 'Polaris', 'F10', and '40rpm-I'. In the center, there are navigation arrows. On the right, a 'Trend' table displays data for four trials. Below this is a 'Formulation' table with columns for property name, units, and values.

Trend				
Polaris	F10	40rpm-I	27/02/20 15:48:40	27/02/20 15:48:43
Polaris	F10	40rpm-II	27/02/20 15:51:28	27/02/20 15:51:31
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Formulation			
BulkDensity	mg/mL		0.5
CarrIndex	%		16.66
Compound10Name			No Data
Compound10Percentage			No Data
Compound1Name			flowlac
Compound1Percentage	%		59.5

Technical solutions - Analysis

- **Time is not the main driver!** The power of **PI Web API Framework**



Conclusion

Challenge

Providing to lab user an application to analyze powder formulations:

- Study of compounds characteristics,
- Find correlation among process variables and formulation variables,
- Optimize process of tableting (machinability),
- Scale-up: find optimal process parameters for large production.

Solution

AVEVA PI System (PI Server, PI Vision, PI UFL connector and SQL Client) for:

- Acquire huge amount of data with no data lost,
- Modelling complex concepts and analytics,
- Provide analysis tool with a weak time dependency,
- Guarantee excellent UX.

Benefits

“One suite for all.”

- No need to use different software to acquire, manipulate and analyze data,
- All data accessible and stored in the right place,
- Easy to adapt to different analysis scenario,
- Interact with different tools and upper systems.

Questions?

Please wait for the microphone

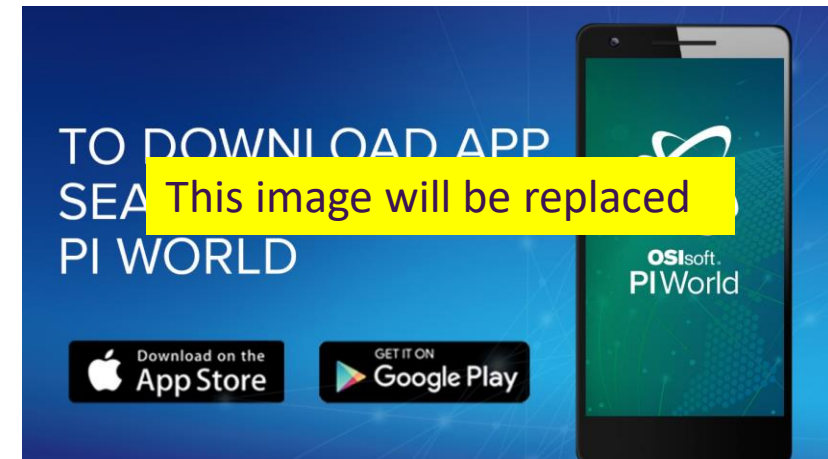
- State your name and company



Please remember to...

Complete the survey!

- Navigate to this session in the mobile agenda for the survey



THANK YOU

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DANKIE

TERIMA KASIH

GRACIES

WHAKAWHETAI KOE

DANKON

TANK

TAPADH LEAT

SALAMAT

SPASIBO

GRAZIE

MATUR NUWUN

ХВАЛА ВАМ

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TEŞEKKÜR EDERİM

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TAK DANKE

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MAHALO IĀ 'ŌE

TAKK SKALDU HA

МЕРЦИ

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PAKKA PÉR

ありがとうございました

DI OU MÈSI

ĐAKUJEM

HATUR NUHUN

PAXMAT CAĜA

SIPAS JI WERE

TERIMA KASIH

CẢM ƠN BẠN

UA TSAUG RAU KOJ

TI БЛАГОДАРАМ


СИПОС


WAZVIITA

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