



Property Mapping:
Whole Process Quality-Critical Influencing Pathways Visualised

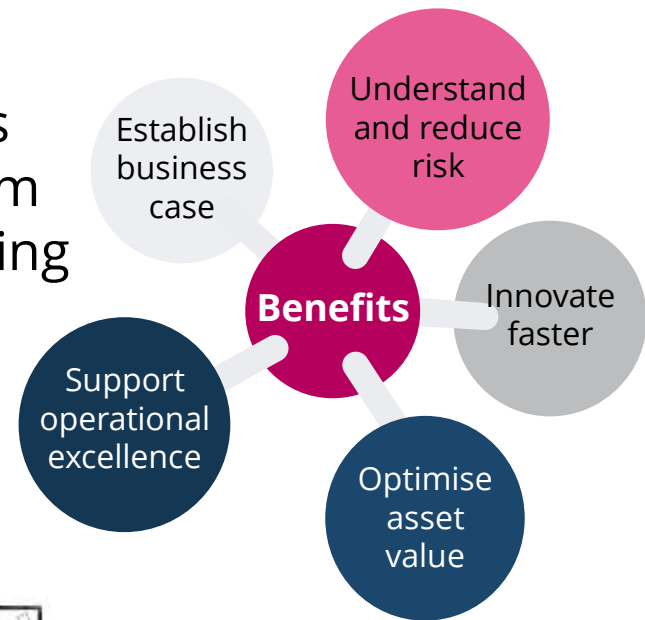
What do I need to get right to make the product right?

Martin Edwards



Our mission

To support organisations to gain tangible value from better process understanding



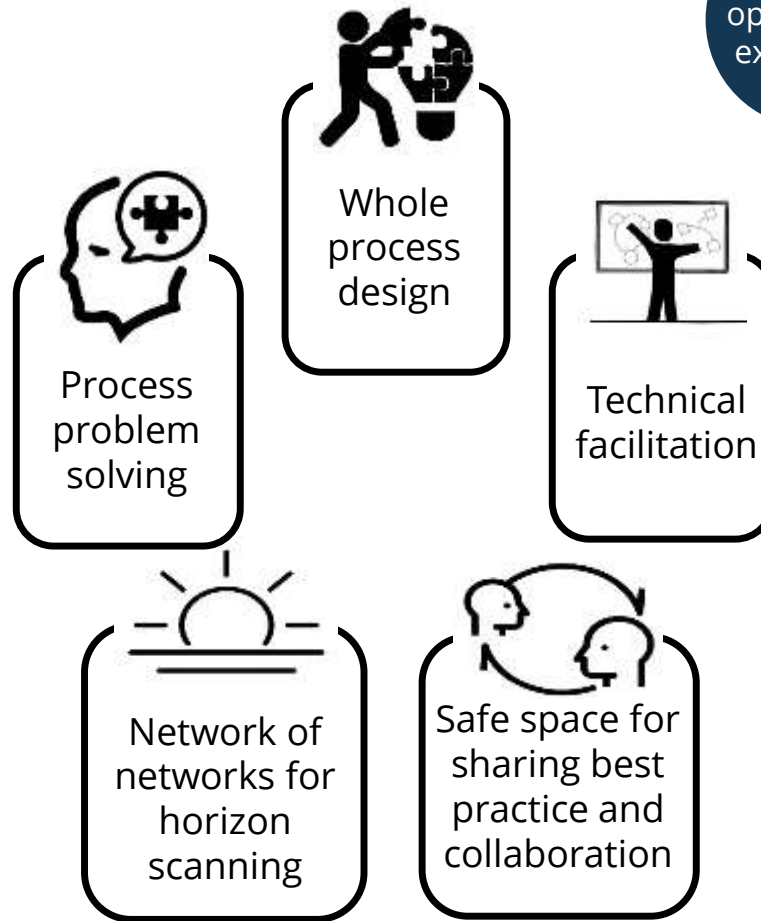
What we do

Help users **define, structure, and translate working knowledge into understanding.**

Enable organisations to embed this approach **to derive business value.**

Members share knowledge and dilute research risk through **a unique collaborative ethos**

www.britest.co.uk



Demonstrated value

- Improved raw material specifications - £350k/yr
- Challenging tacit assumptions in established process - €500k/yr
- Troubleshooting a long-standing filtration problem saved £500k/yr
- Halving batch time enabled >50% throughput increase with no capital investment

Britest Membership and Networks



Industrial Members



Academic Members



Networks



Some Recent Project Collaborations



The D3P logo features the letters "D3P" in a bold, stylized font. The "D" is orange, the "3" is blue, and the "P" is orange. The letters have a glowing, multi-colored border.

Digital Design of Drug Products (InnovateUK)

- Case studies on tablet manufacture by
 - roller compaction
 - twin-screw granulation
- Adaptation of Britest tools for physical processing
- Need to understand and display the relationships between the Critical Quality Attributes (CQAs) and their influencing material and process variables

ReMediES  (AMSCI)
RE-configuring MEDICines End-to-end Supply

ADD  PT (AMSCI)

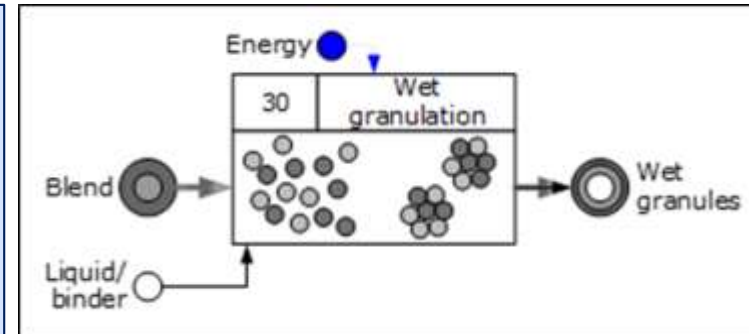
Advanced Digital Design of Pharmaceutical Therapeutics

Examples of Use of Britest Tools in Physical Processing

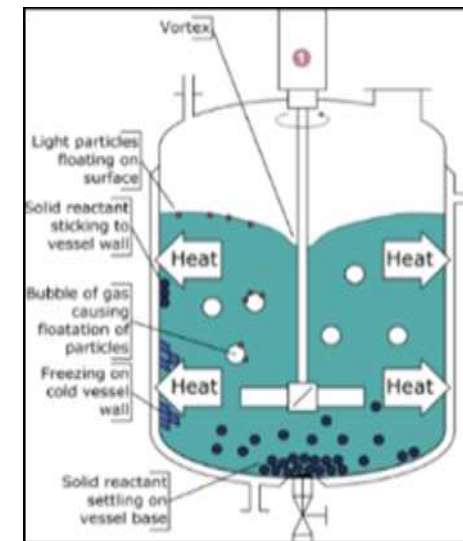


- **Process Definition Diagrams** – processing tasks, process conditions and phases
- **Rich Pictures** – Equipment, product structure
- **TE3PO** – analysis of the materials and equipment involved in a transformation, relevant properties and parameters and the underlying physics

Often need to consider rate processes occurring *in parallel*



Process Definition Diagram (section)

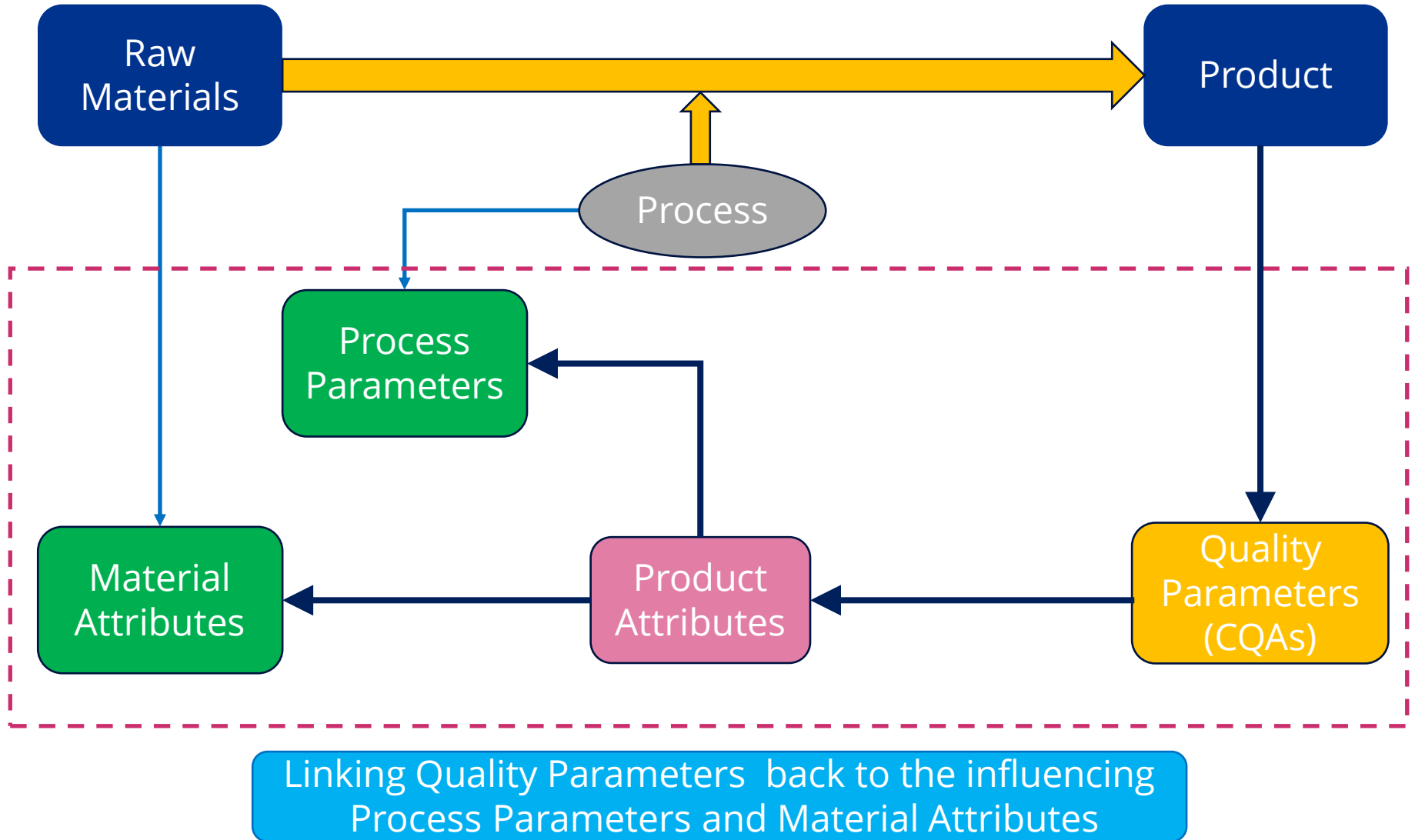


Rich Picture

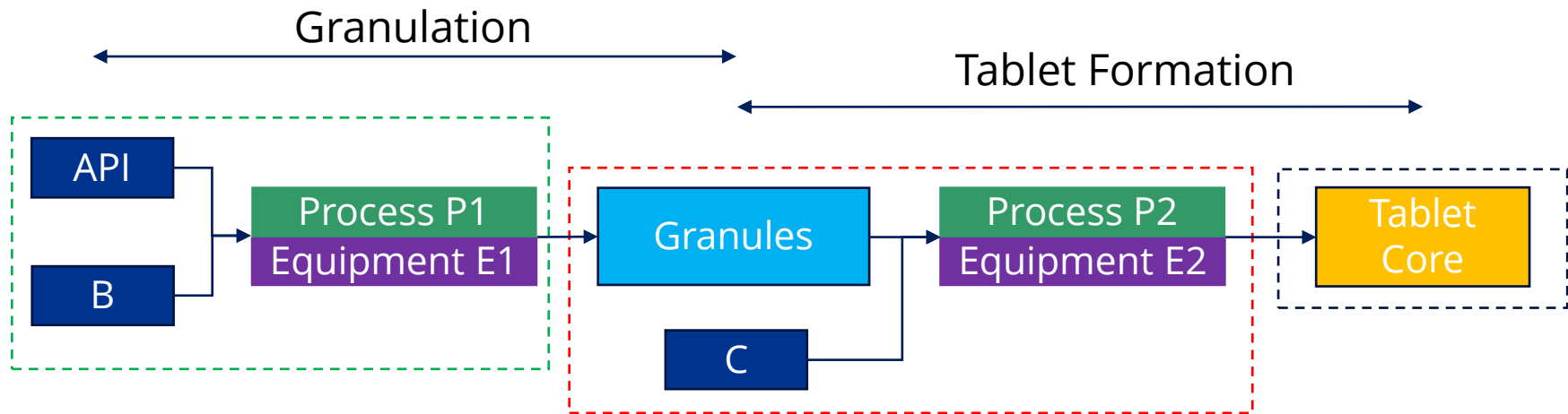
Transformation	Entities	Properties	Physics	Parameters	Order of Magnitude
Liquid flow through bed	Liquid	Density Viscosity	Flow through packed bed (Ergun equation)	Available pressure drop	1 mm/s
	Bed of coffee	Particle size Voidage Bed depth			

TE3PO Table

Overview of Property Mapping Scope

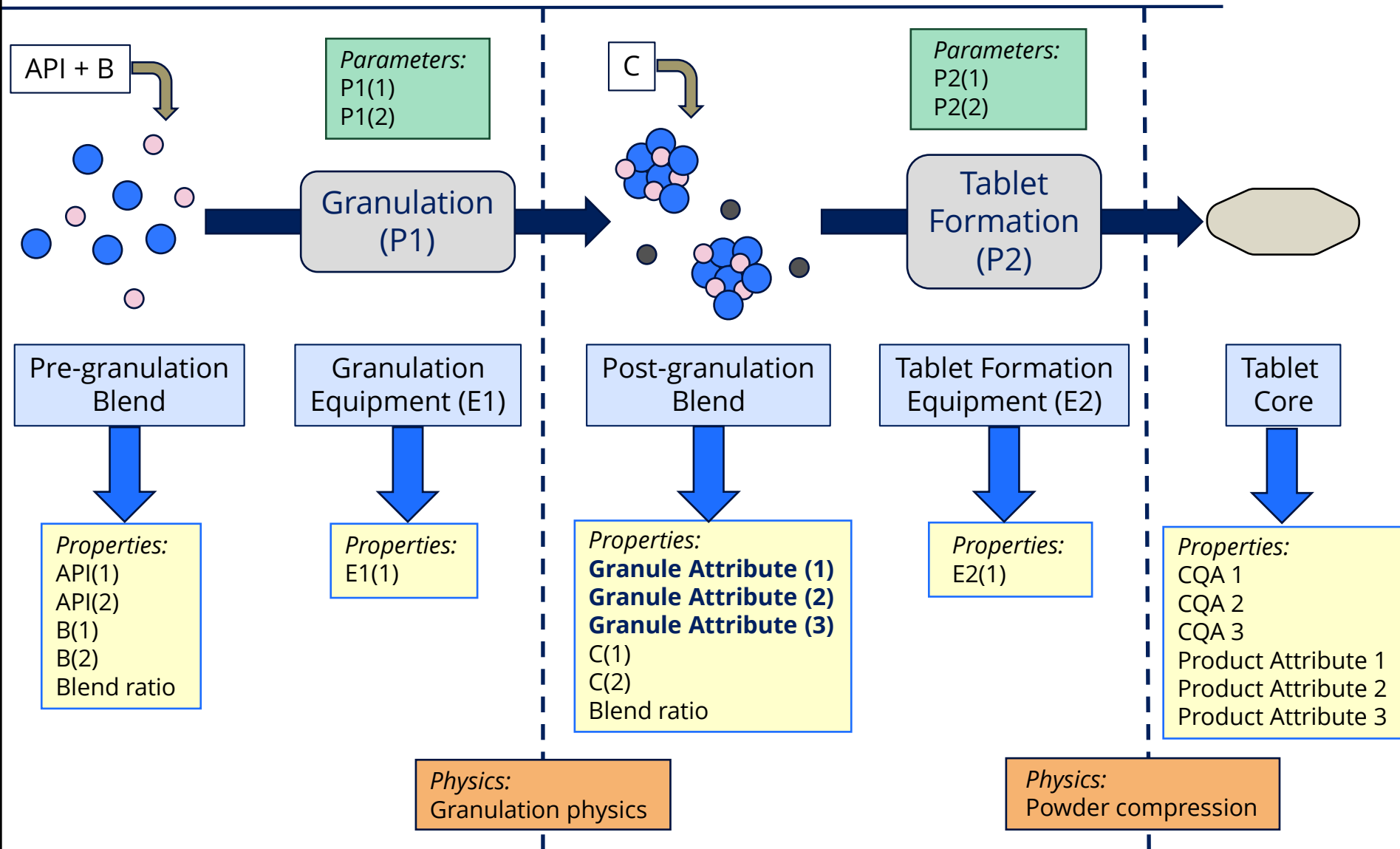


Property Mapping Methodology Applied to a Granulation Process

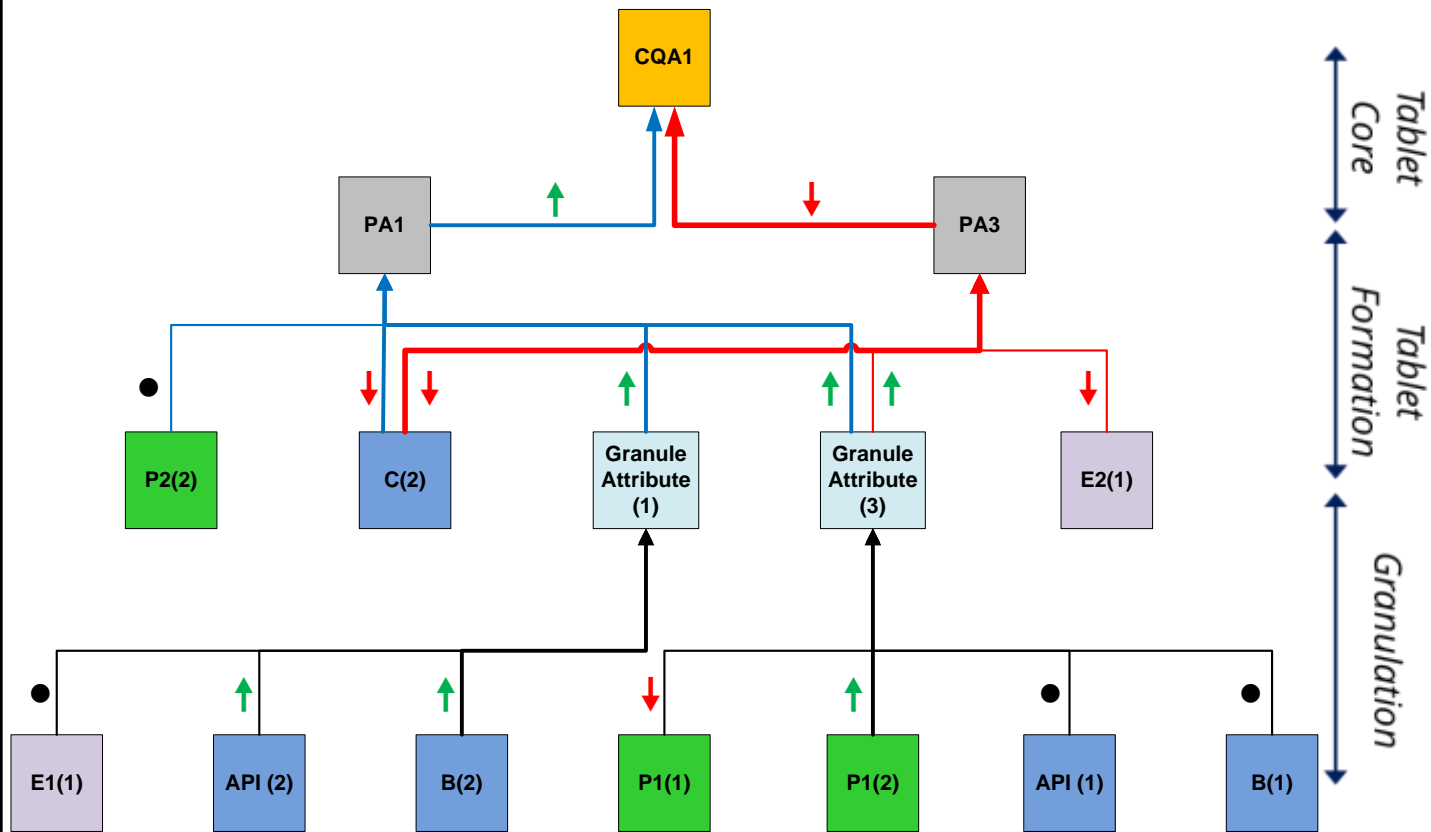


- 1) Describe the product Critical Quality Attributes and any Product Attributes that they depend on
- 2) Link these to the Tablet Formation variables
- 3) Link the properties of the Granules to the Granulation variables

Analysis of Sequential Transformations

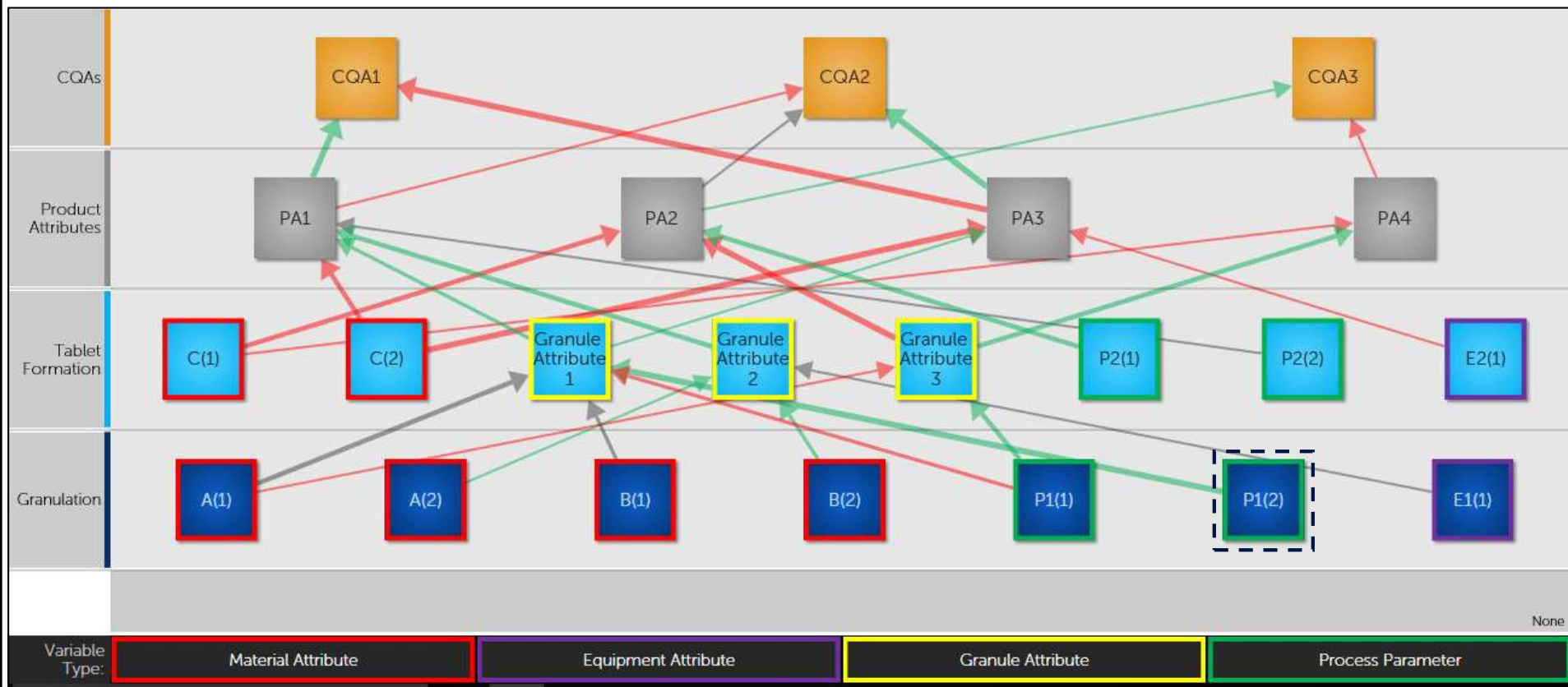


Example of a Property Map for a Granulation Process

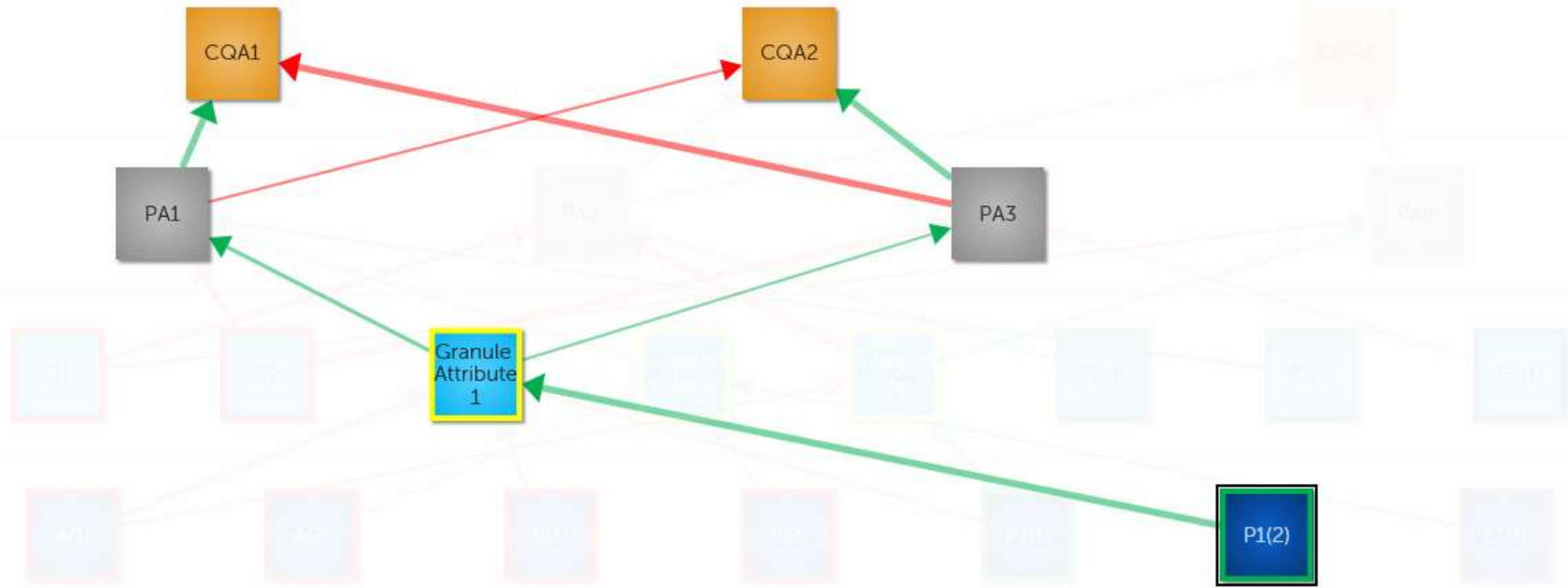


- The Property Map shows the connections from the CQA to the influencing Material, Granule and Equipment Attributes and Process Parameters
- The map captures key properties of intermediates, and how these are influenced by the upstream process step
- Information on the *directionality* of responses can be recorded (e.g. ↑, ↓ or +, -)
- Information on the *strength* of relationships can be displayed (e.g. by arrow thickness)

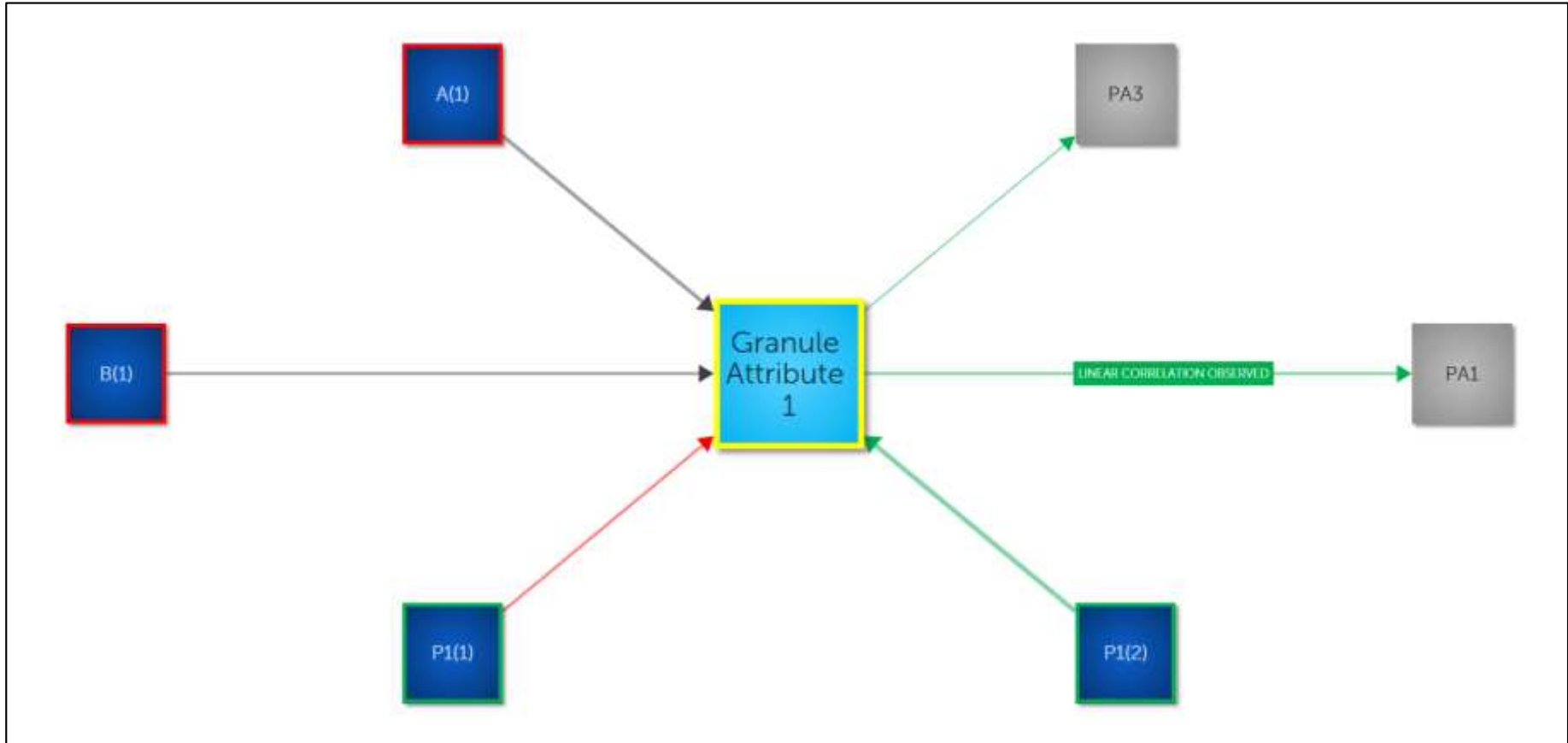
Complete Property Map in SharpCloud for Three CQAs



Selected Detail – Properties Influenced by a Specific Process Parameter



Radial View of Relationships



Property Maps have been built for:

- Roller compaction
- Twin-screw granulation
- Spray drying

Applications include:

- Quality by Design
- Technical risk assessment
- Process troubleshooting
- Process control
- Numerical model building and specification