# Focus, Agility, Speed and Technology (FAST) for Sustainability and Growth

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#### **Editorial**

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## **Keywords**

Extrusion; Lower Cost; Lower Emissions; Predictive Analytics; Time to Market

#### **Abbreviations**

HME: Hot Melt Extrusion; GMP: Good Manufacturing Process; QUB: Queen's University Belfast; IJL: Institut Jean Lamour.

#### Introduction

All countries – even these with moderate debt ratio such as Nordics or Switzerland – now face the question of their resources allocation in order to ensure a profitable path towards sustainability and growth. Some play with the definition of sustainability, some lower their growth expectations, or some advocate the use of tariffs. My opinion is that we could make a better use of technology.

#### Let us be FAST:

Focus on a limited number of issues that have high impact on the well being of our citizens.

Agility in betting on start ups that stay independent while partnering with bigger organizations.

Speed in scaling up breakthrough projects with proper Financing and adequate Team Building.

Technology in developing these that can bring the required breakthrough in performance at the lowest possible cost (cost in capital, operations and unnecessary emissions).

# Vertical Hot Melt Extrusion Is a Good FAST Example

The Hot Melt Extrusion (HME) technology has been used for a long time by the food industry for shaping and

producing foods like pasta or chocolate (or for packaging the food itself), as well as by the polymer industry for building long lasting infrastructure components such as submarine cables or lighter mobility parts such as car body elements.

The use in the Pharma industry was much more recent with the 1st industrial example being this of Kaletra, a combination of lopinavir and ritonavir, initially developed and registered in the USA as a soft gel for the treatment of HIV infections, that was reformulated as a coated tablet for easier transportation, storage and use during the HIV crisis in Africa in 2006. The tablets were manufactured with the original Rondol HME horizontal extruders that mixed the lopinavir/ritonavir with co-polyvinyl ketone and extruded it into granules that were further processed into tablets.

HME Then Developed Quite Well in Its Horizontal Format as It Demonstrated Its Capability to Address Most of The "Usual" Pharma Formulation Challenges:

Pharmaceutical active principles (APIs) are often expensive or only available in limited quantities and therefore need small scale machines in order to minimize and control lot size and manufacturing costs;

Both pharmaceutical grade polymers and APIs are temperature & shear sensitive which requires working on all process parameters in order to lower the shear forces needed and/or the temperatures required to properly mix the final product while avoiding degradation.

Precise dosing of all product ingredients and controlling process parameters with the smallest possible deviation are crucial to monitoring the interference of the API with the other components in the formulation.



The metallurgy of contact parts must not be reactive, additive or absorptive with the product and the equipment must be properly configured for the cleaning and validation requirements (so-called "Good Manufacturing Process", or GMP).

**But work was still needed** to further minimize the quantities of APIs, improve the versatility of the extrusion process, and make both the operator interface, the cleaning process and the GMP compliance more user friendly.

#### And This Is When Rondol Decided to Act FAST:

**Focus** is on developing the vertical format that we see as the next innovation challenge to speed up a broader use of HME for Pharma applications.

Rondol designed and patented (filing in 2016, EU patent in 2019 and US Patent in 2021) our Vertical Extruder that presents a uniquely low footprint of 0.5 m2 compared to 2.5 m2 for horizontal extruders (and the machine is on 4 wheels so easy to move by one single person).

Not to forget a quicker and smoother start to the mixing process, a strong and stable pressure to extract the filament for easier downstream and a more precise process control in real time for temperature sensitive materials.

And in the end a demonstrated efficiency in final product formulation (lower percentage of API or lower number of daily doses for same treatment efficiency) – see Li S, Zhang Z, Gu W, Gallas M, Jones DS, Boulet P, Johnson LM, de Margerie V, Andrews GP, Hot melt extruded high-dose amorphous solid dispersions containing Lumefantrine and Soluplus. Int J Pharm. 2024;124676.

**Agility** Is in Betting on Our Small Structure in Order to Accelerate the Innovation Ecosystem While Leveraging High Level Partnerships.

Rondol nearly stopped all activity but research between 2015 and 2021 and we were able to leverage the results of our research with our partners in academia - Queen's University Belfast (QUB) and Institut Jean Lamour (IJL) as well as in the industry - BASF Pharma, Corealis and Seqens - with whom we work continuously to prove the merits of Vertical HME - see Gallas M, Medjahdi G, Boulet P and de Margerie V, Vertical Hot Melt Extrusion: The Next Challenge

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**Speed** is in developing other than Pharma applications. For example, we recently discovered that combined with innovations such as thin films or 3D printing, vertical extrusion heralds a new era of customization for food applications – see Gallas M & de Margerie V, Vertical Hot Melt Extrusion: A Cutting Edge Technology for Personalized and Sustainable Food Systems, Physical Science & Biophysics Journal, 2024, 8 (2): 000276.

And the development was especially quick for dry battery components. In less than a year, we opened an office in Montreal (November 2024), installed our 1st research line at University of Chicago (January 2025), installed a 2nd research line in our Nancy lab (June 2025) and are getting ready to present the 1st results of our research and partnerships at AABC in Las Vegas (December 2025).

**Technology** is in investing both on the required breakthrough in performance and on the lowest possible associated cost (cost in capital, cost in operation, cost in unnecessary emissions).

The vertical twin-screw extrusion system indeed represents a significant technological breakthrough in terms of precision and efficiency over competing technologies such as dry spray for pharma or compacting of slurry for energy storage while still offering a much lower cost in capital (space optimization), operation (easy cleaning and maintenance) and unnecessary emissions (low energy consumption).

#### Conclusion

As the global population continues to grow and the public money to improve the well being of our citizens become scare, let's hope that intense lobbying in favour of existing technologies that bring lower performance while being more capital intensive with higher operating costs will not slow down the use of a demonstrated precision engineering technology such as vertical extrusion.

Further benefits of vertical extrusion should also come from the use of AI by enabling predictive analytics, process optimization, and quality control. For example, AI algorithms can predict how different ingredient combinations will behave during extrusion, allowing manufacturers to fine tune recipes for all types of applications.