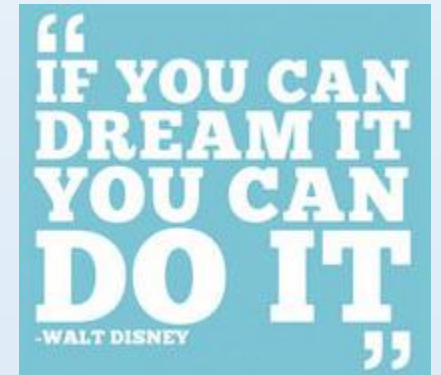


Cross Industries Technology Transfers

Key Success Factors



The Example of Hot Melt Extrusion (HME)

Technology initially developed for processing food and shaping engineering materials

New Use of HME for Pharma applications

A breakthrough process for enhancing solubility of expensive Active Principle Ingredients (APIs) while lowering their scrap rates (on going since 2009)

New Use of HME for Recycling thermoplastic composites

A breakthrough process to develop composites materials "with various recycled content" based on a concept initially developed for recycling multi layers food packaging (starting in 2015)

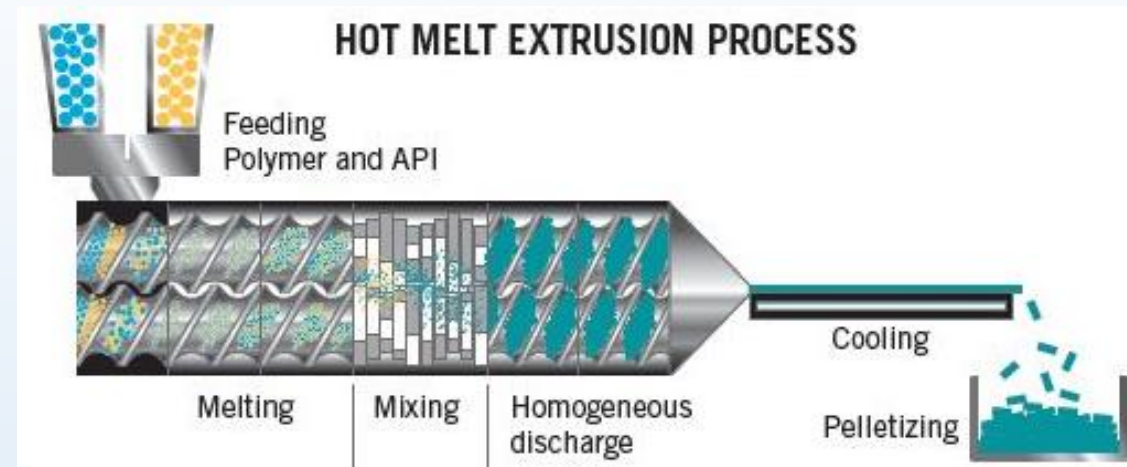


Figure 1. The HME process

HME for Pharma (1): The benefits

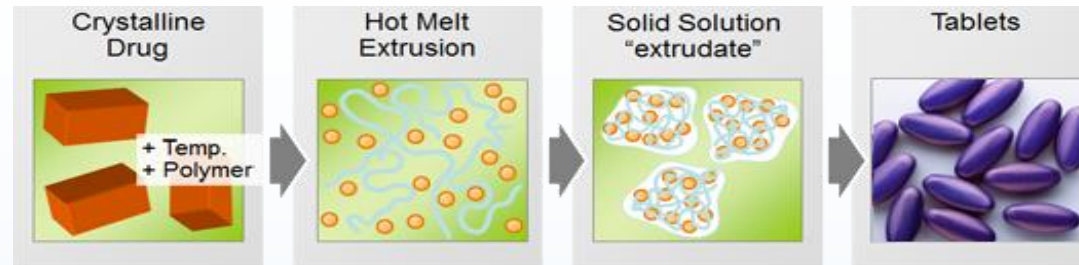
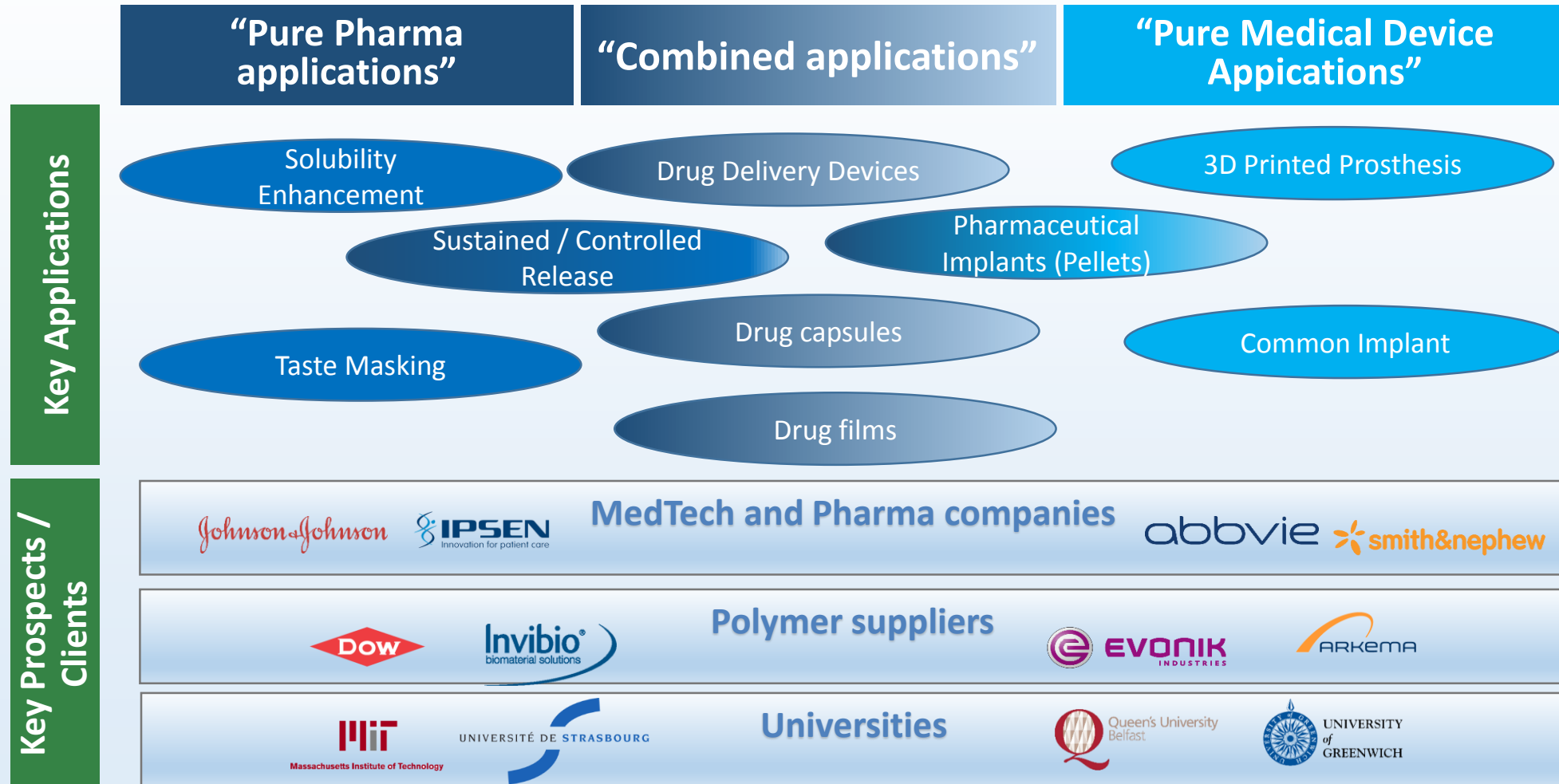


Figure 1. The HME process

Features and benefits of HME for pharmaceutical applications	
FEATURE	BENEFIT
Continuous process	Economical, efficient scale-up
Multiple batch operations	Precise dosing, melting, mixing, degassing, and shaping materials in one single process in short-time
Solvent free processing	Economical and « green », no residual solvent in final product thus waiving need for control stages
Intense mixing and agitation	Improved content uniformity
Process analytical technology	FDA's PAT initiative readily applied, less off-line testing
Extensive automation	Increase productivity, consistent quality products according to GAMP (Good Automated Manufacturing Practice)
Processing of thermally sensitive APIs	Sequential feeding possible in various barrel zones to avoid thermal degradation
Solubility enhancement	Formation of solid dispersions

HME for Pharma (2): Rondol Offering

Pharma / Medtech have successfully tested Rondol equipment at the micro-scale



HME for Pharma (3): A Technical and Human Challenge...

It all started with great enthusiasm

Same great precision of mixing at the microscale allows for targeting industries with very expensive raw materials that require small lot size. Quality is THE issue and not Price (Arthur D Little survey in 2009)

But shareholders found it too long, employees too demanding and customers too far of a support.

Supply of 10 Prototype Lines between 2009 and 2012 (5 to Abbvie in Ludwikshafen, 2 to Catalent in Schorndorf and in the US, 1 to Evonik in Darmstadt, 1 to Ferring in Scotland, 1 to Medtronic in the US).

The solution required further investment and careful consideration

2012: Thorough review (Reims, Freiburg, Gand and Dijon) and selection of Strasbourg as best location for newco with new partners and new CTO from Catalent.

2014: Successful foam extrusion tests for Sanofi, scaling-up to 1st industrial line for Ipsen and nomination at Ubistart award (New York Academy of Sciences)

2015: Chapter in the new HME for Pharma “Bible” (SmithersRapra) and launch of our new “All in One” machine at CPhI World in Madrid



Figure 1. Lafayette Project

HME for Pharma (4): Sustainable Competitiveness

Sustainable Competitiveness thanks to improved patient comfort & lower treatment cost

Obvious Competitiveness....

Longer barrel, chaotic mixing screws, CO₂ injection...offer an extraordinary precision and allow for the production of very small tablets that always have the same percentage of API included.

Less productions steps and resulting lower number of machines allow for much lower capital expenditures and operational expenses.

.... That is Sustainable

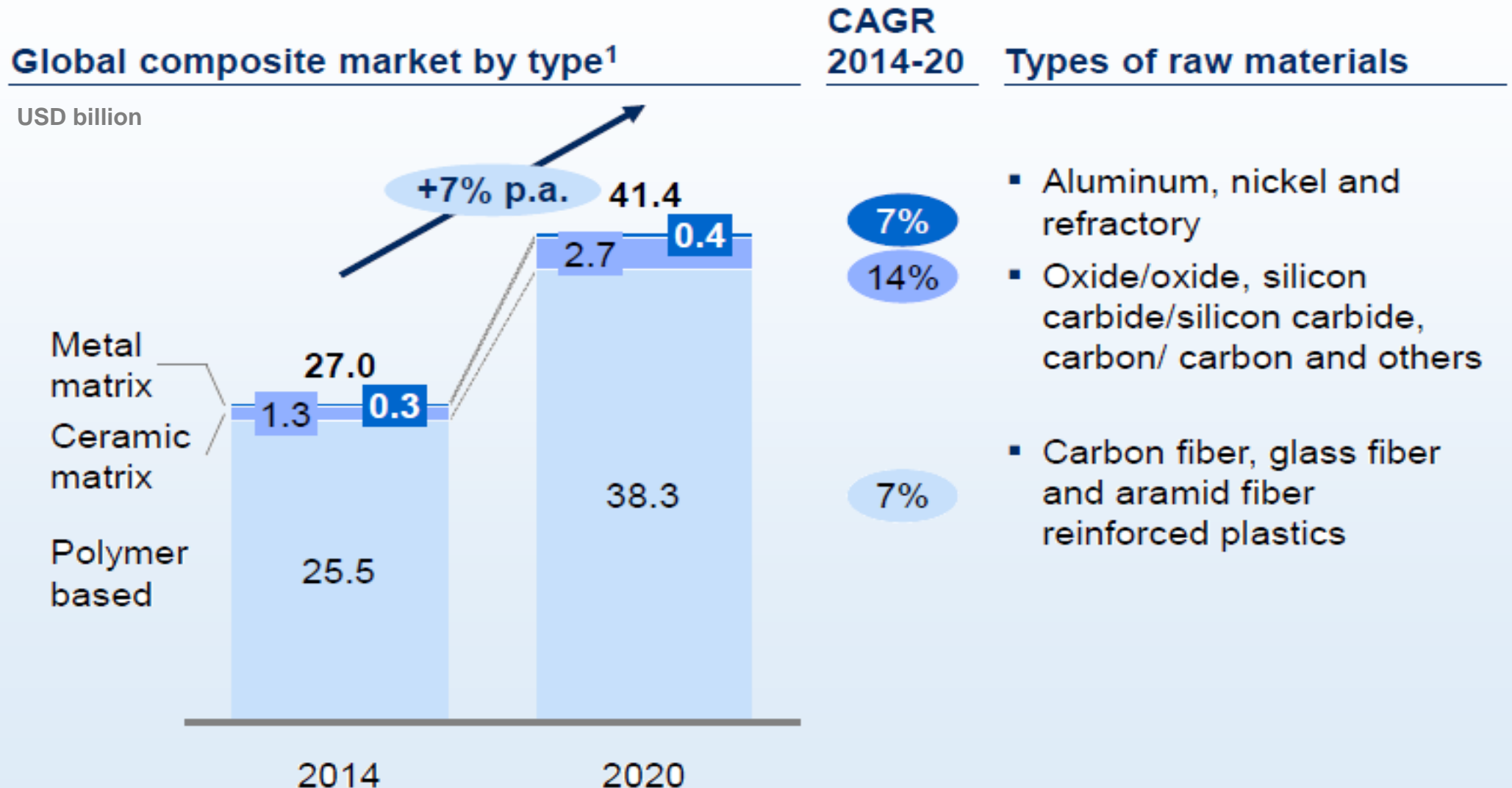
Instead of facing a heavy diffusion session every two weeks at the hospital, the patients will absorb a daily dose while taking one of those tablets at home so that the treatment will be more efficient and comfortable.

It will also spare hospital beds/days which will ease up the constraints on national healthcare budgets all around the world.



HME for recycling Composites (1): The Potential

Global composite market fastly growing and dominated by polymer composites



¹ Composite market as given in: Polymer based Lucintel (March 2014); Ceramic matrix Markets and Markets (December 2014); Metal matrix Transparency Market Research (May 2014)

HME for recycling Composites (2): The Concept

A concept initially developed for recycling multi layers food packaging

Concept of integrating product scrap as a raw material for the fabrication of new products

A concept successfully used in the USA in the 80s along the development of multi layers barrier packaging in order to increase the shelf life of packaged sensitive food such as tomato sauces and "ketchup".

Same concept to industrialize the recycling of high temperature composites (most demanding)

Rondol will now design new type of chaotic mixing screws suitable for processing fibre-reinforced matrices at a minimum of shear in order to avoid stress on critical components, at least the polymer and the reinforcing fibres.

Thorough material characterization needed throughout the full life cycle

At the end of the extrusion/reforming process, prototype materials "with various recycled content" will be further processed to convert them into suitable finished products with specific geometry and shape - while using various technologies such as injection moulding or 3D printing



HME for recycling Composites (3): Project Eagle

For existing apps at similar performance or for new apps at lower cost/performance

Idea initiated thanks to one preparatory call for World Materials Forum in February

Wish expressed by Airbus that the composites recycle chain be industrialized

Collaborative project started by Rondol in March and 4 partners aggregated in 1 month

Arkema (France) will provide composite scrap/"virgin" product, and market information; EMR (UK) will manufacture optimized tooling for stress-free scrap processing, IKT Stuttgart (Germany) will develop and execute analytical procedures for characterizing product performance at all stages along the recycling chain and Greenwich University (UK) will use recycled material for producing finished products with innovative continuous processing technologies.

H 2020 project (4M€) filed by Rondol on April 29th

The intended program covers the entire recycle chain from collecting scrap over the rework process to its reuse in both existing and new applications. A full cost analysis will also be executed for each such application in order to assess its long term viability and help prioritize future research work in that field.

Cross Industry Technology Transfer: Same as Expatriation

You need to learn the language....

The full technical adaptation of our HME machines for Pharma will have taken us 8 years (from the K show in Düsseldorf in November 2007 to the CpHI show in Madrid in October 2015)

... And the same effort is needed to adapt the culture

The same number of years was needed for the “cultural” adaptation and with many more efforts than expected (not only the usual hiring of industry specialists and the “speeches” at various trade shows/conferences but also the application to industry specific awards and even the contribution to the new HME Bible – chapter in the manual to be published by University of Greenwich in June 2015).



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