

« The company's mission is to create value and lower customers' costs, improve quality, and participate in environmental conservation efforts, enabling people to fulfil their ambitions within the company and develop a freer, more «human» way of working. Our mission is to create true value and meaning.»

**Antoine Raymond** *President of the ARaymond Network* 

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# **Press Release**

ARaymondlife continues to develop and commercialize its RayDyLyo® range collaborating with Dara Pharmaceutical Packaging.

The first automated vial-filling line adapted to the new closure device is being previewed at the CPhI in Frankfurt.

RayDyLyo<sup>®</sup>, an innovative device for vial capping

ARaymondlife is a pharmaceutical company GMP EU, specialized in plastic injection molding and fastening solutions. Its technological expertise is applied to develop innovative solutions for the pharmaceutical laboratories (for human health and veterinary medicine) and the medical industry.

Since 2012 ARaymondlife has been offering its own range of patented all plastic caps as an alternative to aluminium crimped closures. RayDyLyo® is more than a product; it is a solution that simplifies and improves the process security of the vial capping operation. Several packaging options are available in bulk or in nests to meet the market's diverse needs. The trend toward ready-to-use components and filling vials directly in nests makes RayDyLyo® a very well-adapted solution.

RayDyLyo® eliminates the need for crimping by pre-assembling the stopper in the cap and closing the vial by simple vertical pressure, either automatically or manually.

• The first filling line adapted for RavDvLvo®

Dara Pharmaceutical Packaging is showing the first vial filling line specially adjusted for distributing and capping vials with RayDyLyo® at the CPhl in Frankfurt (24-26 October 2017).

The Spanish company responded to ARaymondlife's request to develop a vibrating bowl suitable for feeding the all-in-one solution (a stopper pre-assembled in the plastic closure) and the specific parts needed to adapt the line. Pre-assembling the stopper upstream simplifies the process compared to a traditional line by eliminating the stopper placing and crimping operations and saves space in the clean room.

"We want to continue to develop industrial partnerships such as the one with Dara Pharmaceutical Packaging because we are convinced that we are stronger together and that the answers we bring to the market are more relevant." explains Nicolas Thivant, President of ARaymondlife.

 Innovation and diversity are part of ARaymond's DNA

Discovering new markets where its know-how and its potential for innovation make sense has been the driving force behind ARaymond's development for more than 150 years. As one of the world leaders in fastening and assembly solutions for the automotive industry, it has gradually transferred its skills and expertise to new markets: Truck, Industrial, Energies, Agriculture and Life.

"We believe in ARaymondlife's potential because it is an ambitious project driven by the passion and involvement of the people who lead it and it respects the values of our company. We are convinced that our employees' enthusiasm and motivation will make a difference over the long term." says François Raymond, General Director of the ARaymond Network. For the company, diversification also means ensuring its stability and independence despite the political and economic uncertainties that may affect a sector or a country.

# 1.

# ARAYMONDLIFE: INNOVATING FOR THE MEDICAL AND PHARMACEUTICAL INDUSTRIES

# An organization that works with market diversity

Thanks to its experience in assembly and fastening solutions, the ARaymond Network through its company ARaymondlife is putting its values and skills to work for healthcare: technical expertise, quality and innovation. As a Pharmaceutical Establishment, it stands apart from other plastics engineering companies in the healthcare market and therefore has great prospects in product development, news applications, and project management.

ARaymondlife is convinced of plastic's advantages in new developments in the healthcare industry, harmonizing its activities and its organization to support pharmaceutical laboratories as well as players in the medical device and diagnostics industries:

- pharmaceutical activity: The company develops and manufactures its own range of RayDyLyo® packaging products and accessories as well as custom-made primary and secondary packaging for human and veterinary health laboratories.
- medical activity: ARaymondlife designs and manufactures custom medical and diagnostic devices as well as laboratory equipment consumables.

To meet market needs, ARaymondlife inaugurated a new 3700-m<sup>2</sup> plant in Saint-Egrève, outside Grenoble, France, in 2015. The facilities include a technical and logistics area for storing materials, a production area with two ISO 5 clean rooms. Two-storey building of offices include a quality laboratory.

Monitored by ANSES (The French food, environment, and work health and safety agency) who inspects the facilities at least once every three years, the organization conforms to the latest GMP.

"Since the inauguration in 2015, ARaymondlife has set up a second production line in the facility where veterinary medicine for Ceva Santé Animale is produced. A new injection molding machine, a new robot, a new fully automated assembly machine to support this customer in its technical development of the product and its deployment in export markets" says Maxime Bonnet, Delegate Managing Director – Head Pharmacist at ARaymondlife.

ARaymondlife is a business on a human scale and is organized around values shared by all its employees. The company focuses on innovation for the benefit of its customers, to be a genuine partner that is attentive to the development of their needs. For this, the company is developing a managerial system that encourages an entrepreneurial mindset that includes risk-taking, a group effort, and the pursuit of success. Other founding values are collaboration, which requires mutual trust and understanding and creating value for the customer and the company.

Among the 30 employees, there are 2 pharmacists supported by a strong quality team.



 The applications: RayDyLyo® and medical devices

ARaymondlife serves both pharmaceutical laboratories as well as the medical industry

 RayDyLyo®: one of the most innovative ranges on the market

ARaymondlife designed RayDyLyo®, its patented closure device for sterile vials.

Completely developed by the ARaymondlife research office, RayDyLyo<sup>®</sup> is an optimized plastic closure system that offers an alternative to aluminum caps.

In response to regulatory changes related to aseptic filling (according to the recommendations of Appendix 1 of GMP which came into force on March 1st 2010 concerning areas with controlled atmosphere for manufacturing sterile medicines to limit the risks of particulate and microbial contamination), RayDyLyo® offers an all-plastic capping solution. Its advantages:

- the elimination of crimping for liquid and freeze-dried forms
- compatibility with all ISO stoppers and vials
- the pre-assembly of the stopper in the RayDyLyo $^{\!\circ}$  cap
- vial closure using simple vertical pressure, manual or automatic

For the end user, it is easy to use and reduces the risk of damaging gloves.

In addition to the RayDyLyo® product, ARaymondlife offers a range of services, among which are several standard packaging formats compatible with gamma and autoclave sterilization and a wide choice of 11 colors available for the anti-tamper cover.



# 1 STEP ONLY

### RayDyLyo\* SOLUTION

Stopper pre-assembled in RayDyLyo\* cap

### IMPROVED ERGONOMICS

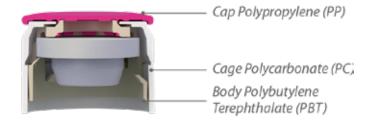
- · Simpler capping, manual or automatic
- · Easy cap removal
- · Less risk of damaging gloves





# SPECIFIC RAW MATERIALS

Medical grades USP Class VI



### AUTOMATED ASSEMBLY

- 100% camera control inspection in production
- 100% control of stopper insertion

ARaymondlife is also launching its own line of RayDyLyo®-specific sterile vial adapters.

The vial adapter allows drugs to be transferred and reconstituted quickly via syringe and for optimal suction of the diluted and reconstituted drug. A RayDyLyo® vial adapter for each diameter (20 and 13 mm) will be available soon so that current users of this type of device on aluminum caps will not be affected by the change of the sealing system.



### RayDyLyo®: an aseptic filling solution

RayDyLyo® is more than a product; it's a solution that simplifies and improves the process security of the vial capping operation. Several packaging formats are offered bulk (ready-to-sterilize) or in nest (ready-to-use) to meet the market's various needs



### Manual

Since February 2016, ARaymondlife and the Disposable-Lab Eurofins Amatsigroup\* (specialized in the aseptic production of technical and clinical batches with single-use equipment) have combined their expertise to offer biotech and pharmaceutical laboratories a global solution for the aseptic filling of innovative biological products. This line is intended for small batches—up to 1,500 vials holding 2–50 mL each—and makes manual filling possible. Closing the vials is easy: the one-step RayDyLyo® sealing system consists of stoppers pre-inserted into the plastic closures.

<sup>\*</sup>In January 2017, Disposable-Lab was acquired by the Amatsigroup group in Toulouse, France, which was acquired by Eurofins Scientific on 30 July, a world leader in biological analysis services for pharmaceutical, food and environment industries.

### **Automatic**

ARaymondlife has also partnered with manufacturers SCHOTT and Vanrx to offer an aseptic filling solution in a fully robotized isolator. ARaymondlife provides its RayDyLyo° closures packaged in nests for easy handling in the automated isolator: the vials are filled and sealed without being removed from the nest. No human intervention is necessary, which guarantees sterile filling.

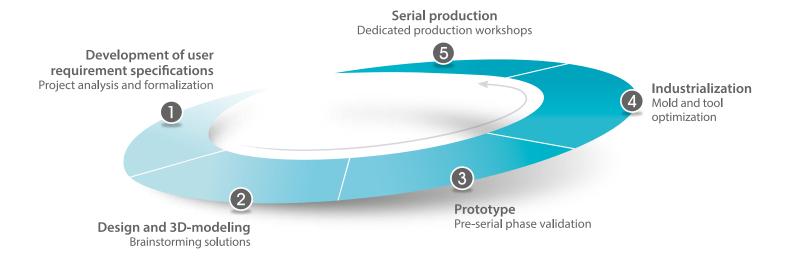


### Medical devices

The company is developing proven expertise in the design and manufacture of single-use medical devices and plastic accessories and offers customized support to its customers for every project.

As a true «solution provider», the project teams provide a full study with innovative concepts incorporating market constraints and objectives. ARaymondlife oversees the development of the approved solution and its integration into the industrialization process. ARaymondlife can rely on other companies in the ARaymond Network for production that does not require a controlled atmosphere.

ARaymondlife's flexibility allows it to direct its expertise to both large pharmaceutical laboratories and biotech start-ups.



**Process of product creation** 



 An interview with Nicolas Thivant, President of ARaymondlife

Could you tell us about the path that led you to become the Chairman of

### **ARaymondlife on 1 June?**

Previously I worked in plastics engineering at Plastic Omnium, then in packaging, and finally in the pharmaceutical industry successively at Amcor (Pechiney at the time), Rexam, and Galderma. ARaymondlife is the natural convergence of these experiences, and this knowledge of both plastics and pharmaceuticals is a proof of trust with our partners and customers. I took on a consulting assignment within the company last year, and I was instantly attracted to the project and the group's values. I liked this family-owned business that could remain French and independent while being present abroad at the same time. The humanist side and the long-term vision match what I look for in a company's culture.

# How is ARaymondlife currently positioned in its market?

Generally, plastics engineers come into the healthcare market through subcontracting. ARaymondlife, however, chose to position itself as a pharmaceutical company from the start, developing products under its own brand, with help from partnerships such as the one with the CEVA laboratory. Meanwhile, the group's ability to innovate and its know-how (bi-injection, overmolding, etc.) allowed it to refine RayDyLyo® and invest in a plant with a long-term vision for developing its business. These strategic choices make us stand out from our competitors.

The market shows promise, even if I think it is more challenging than it was ten years ago. Market demand is oriented towards a more flexible solution to reduce time-to-market for new molecules.

That's why today we are present in two markets: national clients for medical devices and international

clients for RayDyLyo®. There are many competitors; the battle will be won on quality. We know we are well positioned in this aspect, thanks to three international patents that protect RayDyLyo®.

### What are ARaymondlife's ambitions for growth?

In the end, we want to become a major supplier and position ourselves on large production capacity. But for now, we are betting on biotech companies and upcoming molecules with lower volumes but for which we can provide true added value and adapted offers.

«We want to continue to develop industrial partnerships because we are convinced that we are stronger together and that the answers we bring to the market are more relevant. The collaboration with Dara Pharmaceutical Packaging is the culmination of several years of prospecting and analysing existing lines. For 3 or 4 years we have met with them regularly at professional events; we also visited their site in Barcelona. In our collaborative approach, what attracted them was our ability to innovate with RayDyLyo®. They trust us with a project as ambitious as they will be pioneers in their field.

# INDUSTRIAL PARTNERSHIPS THAT BOOST DEVELOPMENT

 A new filling line adapted by Dara Pharmaceutical Packaging

In early 2017, ARaymondlife and Dara Pharmaceutical Packaging teamed up to market the first vial-filling line suitable for capping with RayDyLyo°.

Founded in 1996 and based in Barcelona, Dara Pharmaceutical Packaging manufactures individual equipment and complete lines for washing, sterilizing, filling and closing of bottles, cartridges, syringes and pouches for liquid, semi-solid and powdered products, under sterile conditions.

The company's philosophy is oriented towards quality, innovation, technological excellence and providing the pharmaceutical, biotechnology and cosmetics industries with the most technologically advanced equipment. The company prides itself on its ability to adapt and personalize each project to meet the customer's needs.

 Interview with Joan Melé, Commercial Director, Sales Department Dara Pharmaceutical Packaging

# Why did you partner with ARaymondlife? What were your expectations?

Dara is heavily market-oriented, which allows the company to be open to new customer needs and improving our processes.

For the vial-filling lines, managing aluminum closures is an additional cost and step to handle. This forces most pharmaceutical companies to invest in larger clean rooms and new machines, to manage particle generation problems and requires additional handling of consumables.

After discovering RayDyLyo®, a product that respects GMP directives, Dara wanted to be the first to implement this high-added-value solution and develop all the parts in the required

format for either new machines or to re-equip existing machines.

Data hopes that this collaboration will continue to help customers not just by providing high-quality equipment, but also offering and integrating the latest solutions to make systems more efficient: flexibility, maximizing performance, smaller clean rooms, ease of retrofitting Dara machines, and cost reduction.

# With this new line, what are your ambitions regarding the market?

We believe that this first filling line will be introduced to the market progressively, but we are convinced that this product will gain significant market share in the medium term, as is the case today for RTU products (Ready-To-Use) available in nests. RayDyLyo® is a high-quality product that fits perfectly with Dara's filling lines.

DARA Pharmaceutical Packaging

Carrer de Galileu Galilei, 08403 Granollers, Barcelona, Catalogne

150 employees

90 % of turnover made internationally

60 machines produced per year; 95% for the pharmaceutical industry



# • The first RayDyLyo® filling line dedicated to vials

To encourage market take-up of new packaging solutions, ARaymondlife asked the Spanish company to be the first to adapt a vial-filling line specifically for distributing and capping vials with RayDyLyo®. Equipped with a vibrating bowl suitable for feeding the all-in-one solution (a pre-assembled stopper in the plastic closure) and the specific parts required to adapt the line, it is operational and ready to be marketed. The line will be exhibited in Dara's showroom and occasionally at trade shows in which the two companies participate. Adapting the line with RayDyLyo® presents a major advantage: pre-assembling the stopper makes the process simpler by removing crimping and saving floor space in the clean room

compared to a conventional line. Premiered at the Dara Pharmaceutical Packaging stand at CPhl Frankfurt, the line will be there for on-demand tests to demonstrate how this system can be implemented in an industrial process.

# Other existing partnerships

### Vanrx - Matrix Alliance

Since next-generation drugs require perfect harmony between manufacturing processes and packaging solutions, market-leading suppliers have formed the «Matrix Alliance». Their mission is to market complete and attractive solutions in the field of aseptic filling; consisting of nests of vials and RayDyLyo® closures with pre-assembled elastomeric stoppers, and a filling machine, the solutions will speed take-up of new advanced medicines.

The Alliance was instigated by Vanrx Pharmasystems with the following founding members: ARaymondlife, Daikyo Seiko, the Datwyler Group, Ompi, Schott AG, and Schott Kaisha. The companies combine their efforts on new manufacturing and packaging technologies for pharmaceutical products.

ARaymondlife, Schott, and Vanrx have teamed up to design an aseptic filling solution that uses an entirely automated isolator. The ARaymondlife RayDyLyo® nested solution—Ø20 mm for 6 to 15R vials, and soon Ø13 mm for 2 to 4 R vials—is perfectly compatible with adaptiQ® nested vials designed by Schott, a specialist in primary packaging. Nesting allows manipulation within a completely automated isolator: vials are filled and sealed at the same time in the nest, without denesting. Vancouver-based Vanrx Pharmasystems developed the SA25 Aseptic Filling Workcell for use with injectable medicines.

This RTU solution is unique: it guarantees sterility and repeatability of manufacturing conditions, offers more flexibility - faster drug change between two production cycles - and clearly saves time. No human intervention is necessary, which guarantees sterile filling.

# • Disposable-Lab Eurofins Amatsigroup

Accelerating time-to-market for new drugs depends on several factors—specifically the capacity to quickly develop the first technical, clinical and feasibility batches in the right environment. Complying with best manufacturing practices and keeping costs low are also key.

Single-use technology has the potential to transform pharmaceutical and biopharmaceutical manufacturing through greater flexibility, improved efficiency and guaranteed sterile processing. It also eliminates the need for cleaning solutions and validation. To meet this new need for aseptic filling, ARaymondlife and Disposable-Lab combined their forces in 2016 to offer an easier, reliable, and faster solution.

This solution—the first of its kind—features a Disposable-Lab Eurofins Amatsigroup inflatable single-use isolator and ready-to-use packaging components (Disposable-Lab Eurofins Amatsigroup Pyrofree glass vials combined with RayDyLyo® plastic snap-on caps with preassembled elastomeric stoppers). Clients can set it up in an environment that best suits their needs.

This line is intended for small batches—up to 1,500 vials holding 2–50 mL each—and makes manual filling possible. Closing the vials is easy: the one-step RayDyLyo® sealing system consists of stoppers pre-inserted into the plastic closures.



# 3.

# ARAYMONDLIFE, REPRESENTS ARAYMOND NETWORK'S HEALTH EXPERTISE

An idea mixer serving several markets

From the press-stud button to automotive fasteners and then to fastening solutions for photovoltaic modules, ARaymond's history is one of family and a team of entrepreneurs driven by the desire to derive meaning from working together on a wide range of issues. Internationally, the ARaymond Network's philosophy is to trust local entrepreneurs for its present and future installations and to approve priorities together around shared values. For over 150 years, ARaymond has successfully adapted its model to changing times. Each of the five generations has contributed to the company's success, inspired by its

own historical context.

Discovering new markets where its know-how and its potential for innovation are recognised has been the driving force behind the Network's development for more than 150 years. As one of the world leaders in fastening and assembly solutions for the automotive industry, the ARaymond Network has gradually transferred its skills and expertise to new markets: Truck, Industrial, Energies, Agriculture and Life. For the company, diversification also means ensuring its stability in several markets despite the political and economic uncertainties that may affect a sector or a country.



 Interview with François Raymond, General Director of the ARaymond Network

Innovation has marked the ARaymond Network's history throughout its more than 150 years. How do you keep this

never-ending research going?

At ARaymond, innovation is a state of mind that reflects the need to always question one's self and to continue to provide value to the company's customers. Ever since the start, teams chose to create an offer that stood out; today, it's demanding work, even a challenge, every day for our employees since we can never take anything for granted. I talk about our employees deliberately, because innovation as we see it is not just the preserve of R&D but a common ambition shared by everyone in the company, whether the innovation is incremental or a breakthrough. Everyone in ARaymond is expected to make suggestions to improve our procedures and services. We encourage this mindset within the company and beyond with a large network of partners; for example, ARaymondlife's partnerships with Vanrx, Disposable-Lab Eurofins Amatsigroup, and now Dara Pharmaceutical Packaging is perfect proof.

### Why did the ARaymond Network choose to diversify?

The company didn't wait for the globalization of the past few decades to diversify. Ever since the beginning of its story, it developed skills in glove-making, first in textiles, then in the automotive industry. At the time, this gamble stemmed from the knowledge that our expertise could be transferred to several markets. We continue on this path by providing stand-out value to our customers, adapting ourselves to the constraints of different markets with regard to engineering, design, or industrialization.

For example, today automotive (our first market) also includes motorcycles, trucks, 3-wheeled vehicles and the upcoming driverless vehicles. We want to foster the company's agility to anticipate changes in market segments and identify new trends where we can apply our know-how. We are also present in the agriculture, energy, and, of course, healthcare, sectors where we have already identified many opportunities for the coming years.

The strategic plan for 2030 that we are building will allow us to react quickly and be agile, strengthening our development in our target markets and ensuring our sustainability.

# What is ARaymondlife's share of the Network's overall activity?

ARaymondlife is a proud achievement for the business with strong potential for development in long and international cycles. In 2007, we started an activity where products require several stages of development, qualifications, and approvals before going into production, unlike what we were used to in the automotive market. We took the time needed because it was part of our long-term strategy. We were confident in the future and have trust in our ambitions, because we were convinced we could bring value to our clients and partners. For example, with RayDyLyo® we clearly had a breakthrough innovation that required long-term investment. We were patient and offer this stability to our customers. In our international perspectives, we can also rely on teams in 26 countries to encourage openness and knowledge of local markets, which is a significant advantage and makes sense for a collaborative company like ours.

We believe in ARaymondlife's growth potential because it is an ambitious project supported by the entire network and, above all, by the passion and involvement of the people who work there and respect our company's values. I am convinced that our employees' motivation and involvement will make the difference over the long term.

# THE ARAYMOND NETWORK IN NUMBERS

2016 revenue: €1.1 billion

6 800 employees in 26 countries and across four continents

1 600 active patents

25 000 production items

# **NOTES**

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