



Health Care, **Human Care**

Rafarm's R&D

Department Profile



R&D department goals



01

Quality

Develop high quality products using the enhanced development approach (QbD principles)

02

Competition

Focus on technically challenging or having limited competition drugs (i.e., complex, hybrid)

03

Flexibility

Quick initiation with smart resources utilization to minimize time-to-market and reduce cost

04

Networking

Collaboration to expand capabilities and know-how

Outline

R&D in numbers



Personnel

55+ Scientists



Facilities

2,500 m² area



Equipment

50+ Galenical equipment
70+ Analytical instruments



Projects

16 approvals in last 8 years
7 under submission
10 under development

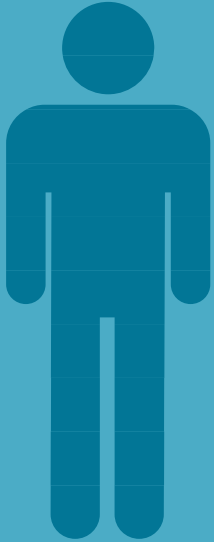


Innovations

3 patents granted

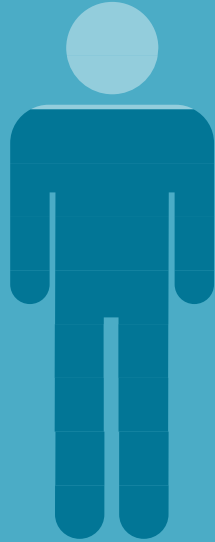
Personnel

Academic degrees



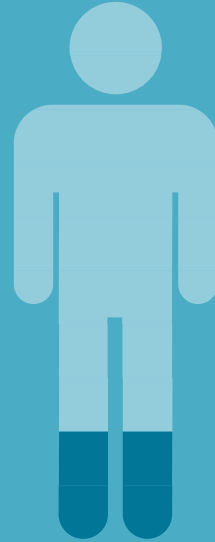
Bachelor

100%



Master

80%



Ph.D.

20%



Post doc

10%

Facilities

New state-of-the-art RnD center (offices and laboratories)



Equipment

Manufacturing capability

Liquid forms preparation

Equipment	Capacity
SS vessels of various sizes	1 L – 150 L
SS jacketed reactor with top-driven mixers or high-shear homogenizers	3 L – 10 L
SS jacketed reactor with top-driven mixer and/or bottom-driven high-shear homogenizer and integrated scale	3 L – 20 L

Mixing / Dissolution

Equipment	Scale
Stirring hotplates (x 12)	100 mL – 10 L
Overhead mixers (x 4)	500 mL – 15 L

Equipment

Manufacturing capability

Homogenization /
Dispersion / High-shear

Equipment	Capacity
Laboratory high-shear homogenizers	50 mL – 20 L
Laboratory high-shear mixers	100 mL – 5 L
Laboratory in-line homogenizer	100 mL – 10 L
Pilot scale in-line homogenizer	5 L – 50 L
Commercial scale in-line homogenizer - Silverson	50 L – 300 L

Size
reduction

Equipment	Capacity
Agitator bead mill	600 mL – 10 L
High Pressure Homogenizer	500 mL – 75 L

Equipment

Manufacturing capability

Nano-emulsification

Equipment	Capacity
High Pressure Homogenizer	500 mL – 75 L

Filtration

Equipment
Filtration device with vacuum pump
Stainless steel pressurized filtration device / Scale-down modeling with Vmax technique

Equipment

Manufacturing capability

Sterilization

Equipment

Moist heat steam autoclave

Aseptic handling

Equipment

Laminar Air Flow cabinets

Glove-box

Filling - Sealing

Equipment

Semi-automatic filling machine

Semi-automatic sealing machine

Automatic closing torque application

Equipment

Manufacturing capability

Auxiliaries

Equipment

Temperature control systems

Peristaltic pumps

Diaphragm vacuum pumps

Analytical balances

Precision balances

Platform scales

Water purification systems

Equipment

Manufacturing capability

Stressing

Equipment

Climatic room for 25 °C / 60% RH

Climatic room for 25 °C / 40% RH

Climatic chambers 30 °C / 65% RH

Climatic chambers 30 °C / 75% RH

Climatic chambers 40 °C / 25% RH

Climatic chambers 40 °C / 75% RH

Photostability chambers

Heating chambers/drying ovens

Freezers

Refrigerators

Equipment

Analytical capability

Sample preparation

Equipment

Magnetic stirrers

Vortex shakers

Platform shakers

Ultrasonic baths

Centrifuge

Incubators

Microbalances

Analytical balances

Precision balances

Equipment

Analytical capability

Chromatography

Equipment

HPLC system with UV detector (x 21)

HPLC system with RI detector (x 2)

HPLC system with PDA detector (x 2)

UPLC system with PDA detector

IC systems with autosampler

GC system with FID and TCD detectors (liquid and headspace sampler)

Equipment

Analytical capability

Spectroscopy

Equipment

UV-Vis with temperature control

FTIR / FTIR-ATR

AAS with graphite furnace and FID

Dissolution

Equipment

Dissolution systems USP I & II apparatus

Dissolution systems USP IV apparatus with automatic sampling

Equipment

Analytical capability

Physicochemical analysis

Equipment

pH meters

Osmometers

Tensiometer

Contact angle

Rheometer

Rotational viscometer

Headspace analyzer

Karl Fischer

TOC analyzer

Conductivity meter

Refractometer

Polarimeter

Equipment

Analytical capability

Particle analysis

Equipment

Laser diffraction with liquid & solid dispersion unit

Dynamic light scattering

Zeta potential (Surface charge)

Light obscuration particle counter

Dispersion analyzer

Microscope with automatic measurement capability

Stereo-microscope

Projects

Route of administration / Dosage forms

Since 2015, mainly focused in sterile products – injectables & ophthalmics



Injection

Solutions

Nano-colloidal solutions/dispersions



Otic

Suspensions



Ophthalmic

Solutions

Suspensions

Nano-emulsions

Lyophilized nano-emulsions

Preservative-Free (PF) formulas

Combination products



Infusion

Solutions

Nano-colloidal solutions/dispersions



Projects

World-wide submissions

North America

USA
Canada

Europe

EU
UK
Several European countries

Asia

China	Iran
Israel	Iraq
Singapore	Kazakhstan
Hong Kong	Uzbekistan
Jordan	

Central / South America

Mexico	Panama
El Salvador	Honduras
Nicaragua	Guatemala
Costa Rica	
Dominican Republic	

Africa

Sudan
Morocco
South Africa

Oceania

Australia



Projects

Achievements *

Approved

15 products commercialized

- ✓ *1st approved by FDA drug product manufactured in Greece*
- ✓ *1st approved by FDA ophthalmic drug product developed and manufactured solely in Europe*

Under development

10 products under development in various stages
3 products undergoing clinical trials

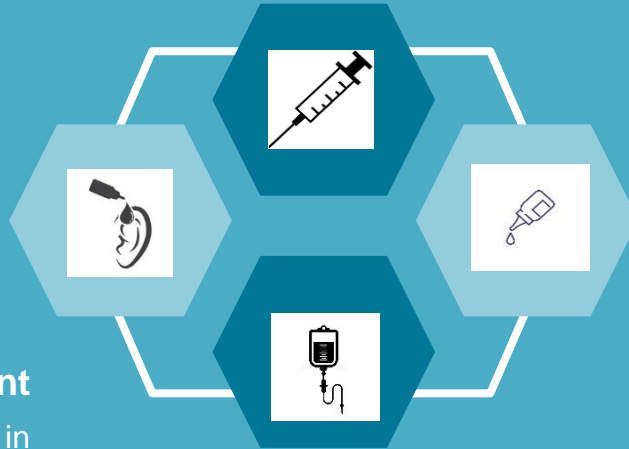
Under submission

7 products submitted

- ✓ *One of few complex drug products approved by FDA*
- ✓ *1st approved by CADTH complex nano-colloidal drug product*

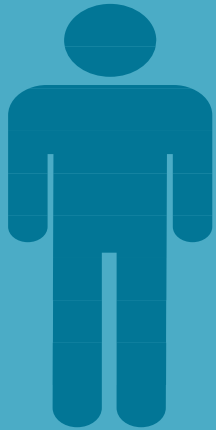
Pipeline

6 new projects to be initiated within Q3/Q4 2024



Personnel from NKUA

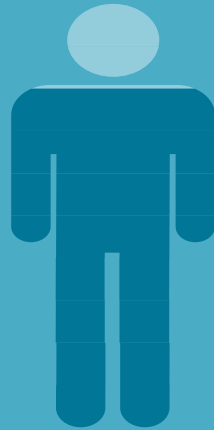
Academic degrees – Start of 2015 to end of 2023



Bachelor

100%

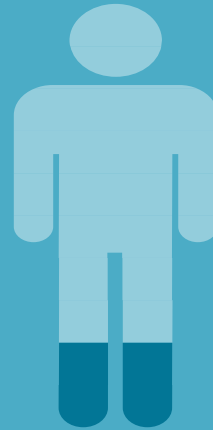
30 out of 50



Master

80%

8 out of 12



Ph.D.

20%

7 out of 10



Post doc

10%

2 out of 5

What is the Pharma Industry's focus for RnD personnel

"Quiver" of Skills/Character/Assets

Candidates for Pharma Industry's RnD

Graduates of Science fields – Pharmacy / Chemistry / Chemical Engineering

Efficiency skills

Awareness of job role / requirements
Guidance/instructions positive acceptability
Adequate comprehension of the tasks assigned
Objective focus / Subjective judgement
Adaptability
Productivity vs Quality
Reliability
Consistency

Technical skills

Theoretical & Technical background – level of knowledge
Capability of technical document composition
Fluency in English (verbal/writing)

What is the Pharma Industry's focus for RnD personnel skills

"Quiver" of Skills/Character Assets

Personality/Behavior

Responsible
Subjective/objective according to needs/tasks
Initiative
Professional
Knowledge diffusion
Cooperative & committed with the team
Cooperative with 3rd parties

Specialized skills/attitude

Organizational
Prioritization
Innovative
Orthogonal & Out-of-the-box thinking
Observative
Problem-solver
Commitment
Willingness to evolve
Willingness to undertake new tasks

Link among Universities & Industry

What is missing today in Greece??

Industry doesn't "approach" Universities and *vice versa* – no communication "channels" available
⇒ only in the recent years, research programs were funded that focused on bridging the two entities
(e.g. EPAnEK - Research-Crete-Innovate, Technology Transfer Offices)

Undergraduate/post-graduate programs lack the envision of working in the Greek Industry
⇒ i.e. most graduates are employed as QA/QC personnel, yet no Quality-oriented course is present in the Universities

No post-graduate programs for **applied** pharmaceutical technology

"Professional orientation" courses are lacking in all educational grades, even in Universities

Steps forward

Universities implementing “dedicated/structured” visits for under/post-graduate students in the Greek Industry sector of interest, for familiarization

Greek industry should take the initiative to state its needs to the respective Universities and further collaborate to provide joint courses/seminars on applied pharmaceutical technology

Post-graduate programs with courses (practical exercise) in collaboration with the Industry
⇒ at least 3 – 6 months in industry environment

Joint actions for establishing a Legal Framework for linking Industry & Universities
⇒ employment contracts, IP commitment etc.



Thank you

for your attention