WORKFORCE OF THE FUTURE
ACADEMIA – INDUSTRY INTERACTION
GPMLF INITIATIVE - AUGUST 2022

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WORKFORCE OF THE FUTURE – OVERVIEW

- The Global Pharmaceutical Manufacturing Leadership Forum (GPMLF)
- The Team
- The reasons for action
- Guidance received from GPMLF
- The Perceived Gaps
- The Approach
- Courses to consider & New Programs
- Industry Contribution

WORKFORCE OF THE FUTURE – TEAM IS SPONSORED BY THE GLOBAL PHARMACEUTICAL MANUFACTURING LEADERSHIP FORUM (GPMLF)

- The Global Pharmaceutical Manufacturing Leadership Forum (GPMLF)
  - Group of **senior global leaders from Manufacturing, Engineering and Quality** in the Pharmaceutical Industry
  - **Strategic vision** of industry trends and developments
  - **Sponsors** task forces with topics leading Industry into the future
  - **Interacts** regularly with representatives from **major regulatory authorities** to discuss emerging topics and needs

- ISPE provides support and the framework to ensure that the outcome of the various Task Forces is communicated and acted on

WORKFORCE OF THE FUTURE - THE TEAM

13 MEMBERS WITH A BROAD PERSPECTIVE ON THE INDUSTRY

- Ferdinando Aspesi – BAI (Co-Leader)
- Tara Tibbs – Eli Lilly
- Ranjit Deshmukh – Astra Zeneca
- Darren Dasburg – CRISP Biotech
- Manfred Maeder – Novartis
- Tony Moreira – UMBC (Co-Leader)
- Meli Gallup – Genentech
- Tina Self – Bayer
- Robert Famiglietti – J&J
- William Clark – Purdue Univ.
- Jo Davisson – Purdue Univ.
- Roe Mingioni – Takeda
- Joseph Sanchez – Merck & Co.

WORKFORCE OF THE FUTURE – THE ISSUE

- Industry needs in the next 5- 10 years across the world a highly skilled workforce with competencies that differ from the past
- Examples are continuous manufacturing technologies, 3D-Printing, combination products, automation, robotics , big data management, …

- The issue
  - Shortage of these resources
    - e.g. Biotechnology gap
      - 5,000 – 7,000 Highly skilled professionals
      - 20,000 – Highly skilled operators and supervisors
  - Geopolitical and social considerations where the pharmaceutical industry is going

GUIDANCE RECEIVED FROM THE GPMLF (I)

- Focus on addressing gaps in professional roles for the following areas
  1. Small Molecules (API) and Drug Products
  2. Biotech Drug Substance & C&GT manufacturing
  3. Delivery Systems and Combination Products
  4. Cold Chain Distribution

GUIDANCE RECEIVED FROM THE GPMLF (II)

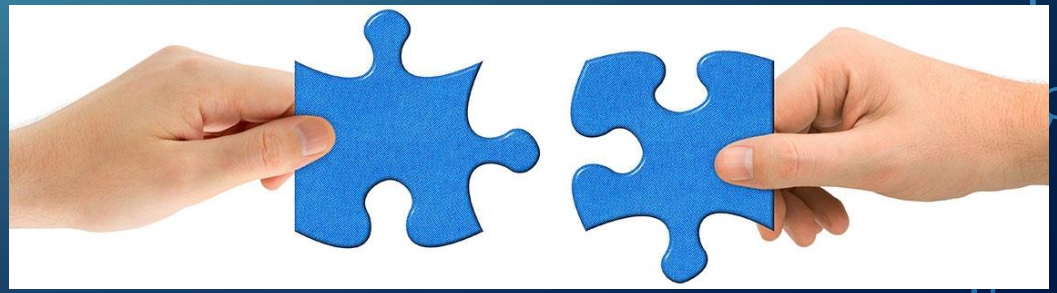
- Integrate Geopolitical and Social Considerations that impact the Pharmaceutical Industry at large
  - Biotech remaining in the western world plus Singapore and South Korea
  - Small Molecules continuous manufacturing in the western world; Low cost manufacturing in emerging economies
  - Delivery Systems and Combination Products – western world
  - Cold Chain Distribution – globally

GUIDANCE RECEIVED FROM THE GPMLF (III)

- Team decided to pursue first industry roles that are needed across the US network of manufacturing sites
- Operators have not been considered as target group initially because their training is addressed by Community Colleges and by Company internal training programs

WHY THIS INITIATIVE IS DIFFERENT

- Our goal is to educate future Pharmaceutical Professionals ahead of joining the job market
- Industry wants in the long term to sustain and continue interactions with Academia
- We aim to work with Academia to develop integrated University curricula that will facilitate these professionals to have in immediate impact when they join the Industry
- We look for Industry and Academia interaction that will allow Academia to be involved in the Industry Innovation and Manufacturing and Control Process Management



WORKFORCE OF THE FUTURE – APPROACH

- The WFOTF team decided to approach the task by creating technical profiles that describe the following aspects of the identified role
  - Personal specification
  - Functional skills
  - Roadmap to 2023 which describes how to get there

- This approach ensures a comprehensive view of requirements and expectations for all stakeholders
  - Industry (incl. HR for hiring purposes)
  - Academia
  - Individuals who are either looking for further qualification or starting their professional career and want to understand where the needs are

WORKFORCE OF THE FUTURE – TECHNICAL PROFILES OVERVIEW

- **34 technical profiles** are available covering the four critical need areas
  - Small Molecules (API) and Drug Products
  - Biotech Drug Substance
  - Delivery Systems and Combination Products
  - Cold Chain Distribution

- They have been **developed by subject matter experts in their field of expertise** and represent a common understanding of all aspects that a role encompasses

PROFESSIONAL PROFILE(COMPETENCIES)
PROFILE - *PROCESS ENGINEER – API/DP*

Person Specification	Enthusiasm to trial new approaches Take informed risks Ability to lead cross functional teams and prioritise CMO Relationship Management Skills (Globalization) Cross culture awareness Flexibility – internation		Example
Functional Skills	**Deep Development** **technology transfer** Process Performance Validation Expertise **Strong Statistical A**		lls
Education	B. Chem. / Mech. En		
Training	**R&D engineers rota** **(Graduate program D** Merge R&D and Technical Operations Training Curricula		**for Global Team Collaboration**
Roadmap 2022	**Applied university programs focus on R&D, TT & Mfg** (focus on current / future regulatory expectations)	**Horizontal company development rotations to build skills and E2E understanding** Statistics in R&D/Mfg for design, dev and mfg requirements	**People and Culture Focus** Understand yourself, different styles & cultures (growing globalization), operational excellence

For more examples, see back-up slides

WORKFORCE OF THE FUTURE
INDUSTRY – ACADEMIA INTERACTION

- Engagement
  - Phase I – Engagement with the US Academia on 5 Technical Profiles
  - Phase II – Engagement with the US Academia on 7 additional Technical Profiles
- Target (US)
  - Master Courses Program
  - Elective Masters courses can also be offered to advanced undergraduate students
- Focus (US)
  - Elective Courses
  - Industry Involvement

WORKFORCE OF THE FUTURE
PHASE I - PROFILES

- Phase I
  - Combination Products Engineer
  - Regulatory Science Specialist
  - Biotechnology Process Engineer
  - Risk Management in Biotechnology Manufacturing
  - IT/Data Management & Analytics Engineer – Short course UC Davis

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PHASE II - PROFILES

- Phase 2
  - IT - Data Management & Analytics Engineer
  - Automation & Robotics Engineer
  - Bioassay Scientist
  - Immunologist
  - Cell Line Maintenance Engineer
  - Cold Chain Packaging Engineer
  - Cold Chain Import/Export Compliance Specialist

WORKFORCE OF THE FUTURE – WORK UNDERWAY

- The GPMLF Team has compared the needs described in the Technical Profiles and what courses and subjects are available at the following Universities
  - Purdue University
  - University of Maryland
  - Rutgers University
  - UC Davis
  - MIT
  - University of Waterloo/Canada
  - Xavier University
  - Penn State University
  - Texas AM

WORKFORCE OF THE FUTURE
UNIVERSITIES CHOSEN FOR THE INITIATIVE

- University of Maryland Baltimore County (UMBC)
- Purdue University – Indiana
- University of California - Davis

- Several courses and programs are underway at these Universities
- There are no plans to initiate these activities in EU and ROW

WORKFORCE OF THE FUTURE PERCEIVED GAPS

We have identified the following gaps (top 7)

A – Combination Products & Delivering Systems

B – Robotics & Automation

C – IT- Data Management –Data Analysis, Modelling, DOE, Statistics and Data Visualization

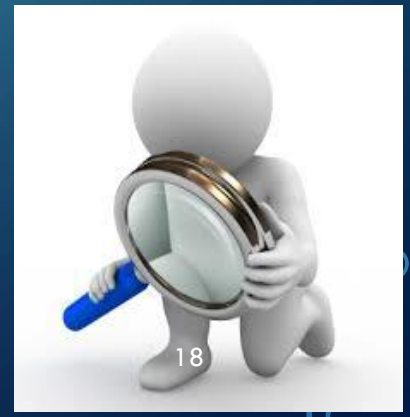
D – Regulatory Sciences, cGMP's and GMP's hands on training

E – Project Management including Risk Management in Manufacturing Processes (Biotech & Small Molecules) and related cost analysis

F – Process Analytical Technology to achieve Real-Time-Release

G - Cell & Gene Therapy Manufacturing

E – Industry internships, seminars/lectures, capstone projects



INDUSTRY – ACADEMIA INTERACTION

- Industry Contribution
  - Assist identifying tracks, certificates and elective courses
  - Provide internships
  - Provide seminar/lecture speakers
  - Provide Masters capstone projects
  - Serve on program advisory boards

BACK-UP SLIDES

- Additional Examples of Role Profiles
- Additional Information about identified Gaps

PROFESSIONAL PROFILE (COMPETENCIES)
PROFILE – *BIOASSAY SCIENTIST*

Person Specification	Collaborator Cross cultural awareness with good communication (written and verbal) and interaction skills that enable effective collaboration with multidisciplinary teams both within and outside the company. Self starter with ability to take informed risks Analytical and continuous improvement mindset		
Functional Skills	Performing receptor activity assays and must be able to apply novel strategies and technologies to facilitate development of performing GPCR expression platforms	Biotech DS/ DP manufacturing experience Method development and validation Strong statistical acumen	Proven project management skills Proven Change management skills Business Acumen
Education	Bachelor / MSc. Degree in analytical science, Biology, Biochemistry	Experimental design experience	Network includes global groups (i.e. professional societies, industry forums, social media, etc.)
Training	Hands-on experience developing and implementing cell-based assays. Hands-on experience in molecular and cellular biology techniques and methods.	Working knowledge of cGMPs Working knowledge of GPCR trafficking and screening.	Virtual management training for global collaboration
Roadmap 2022	Applied programs on life cycle management of methods	Data analytics in manufacturing design Training in separation science and impurity testing	People and Culture Focus Understand yourself, different styles & cultures (growing globalization) Operational excellence

PROFESSIONAL PROFILE (COMPETENCIES) PROFILE – *IMMUNOLOGIST*

Person Specification	Creative and strategic thinker, with the ability to manifest thoughts to actionable contributions. Cross cultural awareness with good communication (written and verbal) and interaction skills that enable effective collaboration with multidisciplinary teams both within and outside the company. Self starter with ability to take informed risks		
Functional Skills	Conduct scientific studies examining cell reproduction and the diseases that affect the immune system, such as allergies and cancer.	Biotech DS and DP development experience	Proven project management skills Proven Change management skills Business Acumen
Education	Bachelor / MSc. / Ph.D. Degree in immunology, Biochemistry, Biophysics, or related field	Hands-on experience with unit operations Experimental design experience	Network includes global groups (i.e. professional societies, industry forums, social media, etc.)
Training	Cross training with R&D, QC and Regulatory	Working knowledge of CMC regulatory requirements Working knowledge of cGMPs	Virtual management training for global collaboration
Roadmap 2022	Applied university programs focus on R&D & Mfg (focus on current / future regulatory expectations)	Horizontal company development rotations to build skills and E2E understanding.	People and Culture Focus Understand yourself, different styles & cultures (growing globalization) Operational excellence

PROFESSIONAL PROFILE (COMPETENCIES)
PROFILE – *BIOLOGIST/ CELL LINE ENGINEER*

Person Specification	Analytical and continuous improvement mindset Cross cultural awareness with good communication (written and verbal) and interaction skills that enable effective collaboration with multidisciplinary teams both within and outside the company. Self starter with ability to take informed risks		
Functional Skills	Cell line development and optimization, gene manipulation and cell transfection	Biotech DS/ DP manufacturing experience	Proven project management skills Proven Change management skills Business Acumen
Education	Bachelor / MSc. Degree in Biotechnology/ Biology	Experimental design experience	Network includes global groups (i.e. professional societies, industry forums, social media, etc.)
Training	Biologist cross training with process engineers and validation, QC	Quality and regulatory requirements (e.g. FDA, GLP, cGMP, USP, CRF) training	Virtual management training for global collaboration
Roadmap 2022	Applied university programs focus on R&D, TT & Mfg (focus on current / future regulatory expectations)	Horizontal company development rotations to build skills and E2E understanding.	People and Culture Focus Understand yourself, different styles & cultures (growing globalization) Operational excellence

PROFESSIONAL PROFILE (COMPETENCIES)
PROFILE - *AUTOMATION & ROBOTICS ENGINEER*

Person Specification	Demonstrated ability working in diverse matrix teams Cross functional Collaboration Strong data-based decision making capability Continuous Improvement Mindset		
Functional Skills	Proficiency in provision of automation services (incl. PAT Sensors, PLC, DCS) IT Infrastructure Expertise Process Control Strategy Expertise Cobots understanding Robotics understanding	Automation Data Analytics Data Historian & vertical data Expertise in Traditional & Continuous pharmaceutical manufacturing E2E Process Automation Understanding Knowledge Pharma 4.0 approaches	Proven project & change management skills Business Acumen Industry Automation Network (affiliation)
Education	Bachelor / Masters degree in Automation / Engineering	Fundamental understanding of Robotics (redesigning processes, finished product) Robotics in Cell & Gene Therapy	
Training	Trained at commercial manufacturing / launch sites (GMP, Process & Equipment Validation)	Training in laboratory systems (R&D, Quality, Manufacturing Science & Technology) Horizontal company development rotations to build skills and E2E understanding	Virtual Management training for Global Collaboration (manage through influence)
Roadmap 2022	Applied programs on understanding of Enterprise Systems and Technologies	University placements in R&D/Mfg for design, development and commercial mfg automation requirements	People and Culture Focus Understand yourself, different styles & cultures (growing globalization) Operational excellence

IT DATA MANAGEMENT AND ANALYTICS

Consolidated Industry Expectation	Skilled analysts & technologies to turn available data into valuable business insights ➢ Data Management ➢ Quantitative Analysis ➢ Interpretational Capability Cyber security is a consideration for industry	
Techniques	Database management Data warehousing Statistical software packages Data analytics and modelling (including data mining solutions)	Data Visualization techniques (Real-Time Monitoring for Decision Making)
Technologies	Excel (tabular information) Spotfire (visualization) Tableau (visualization) Crystal Reports Minitab & JMP (Statistical Tools) Umetrics	Cyber security – knowledge on how to manage critical data Mobile and scalable technologies within inter-company network (cell, phones, tablets)
Outputs	Business Reports Predictive Models Simulation Tools (scenarios) Technical SME Presentations Executive Presentations	Visual Dashboards

REGULATORY SCIENCES

Regulatory Science is the science of developing and manufacturing FDA-regulated products; it enables the assessment of the safety, effectiveness, quality, toxicity, public health impact or performance of these products.

- Drug Substance, Drug Product, Medical Devices 21CFR 314, 200, 600 & 800 (IND, NDA, BLA, etc.)
- CMC – Chemistry, Manufacturing and Controls section of the regulatory dossiers
- ICH Q1a to Q14
  - Examples – Stability , DOE, Product & Process Design, Established Conditions, Validation, Comparability, Risk Management, etc.
- Regulatory Processes
  - US FDA, EMA, European National Agencies, PMDA, etc.
- cGMP's – CFR 210 – 211 - Sub Part A to K – Minimum Current Good Manufacturing Practices for preparation of drug products for administration to humans and animals

PROJECT MANAGEMENT (II)

- Next Level: Strategic Project Management as a capability includes: creating a vision, gaining political support and how to sustain change

  - Governance: continuous improvement of collection, analysis & reporting of project information
  - Hierarchy: project, program management (multiple projects), portfolio management (multiple programs)
  - Emphasis on Risk Management, Management Control, Resource Management & Financial Management

DELIVERY SYSTEMS AND COMBINATION PRODUCTS (I)

- "Combination product" is a terminology used in the US regulation.

  We have to comply with the FDA combination product rule.
- Combinations of Drug/Device or Biologics/Device are considered as Combination Products.
- More than 90% of biologic drugs are marketed as combination products
- Regulation in the European Community is different.
- Regulatory and legal expectations are growing fast in an increasing number of countries worldwide.

DELIVERY SYSTEMS AND COMBINATION PRODUCTS (II)

In order to be able to develop devices specific skills are needed, for example:

- Engineering
  - Device technology expert
  - Risk manager
  - Expert for Packaging –Technology
  - Human Factors expert
  - Transfer engineer
- Pharmacy
  - Quality Control & Testing
  - Human Factors expert