

# Curriculum Vitae

## I. General Informations:

1. First Name:	Ylber
2. Surname:	Qusaj
3. Nationality:	Kosovar
4. Date of Birth	05.04.1983
5. Birthplace-Municipality	Pllajnik-Dragash
6. Gender:	Male
7. Contact details:	1. Pllajnik-Dragash, 2. Unterfeldstrasse 6, 4332 Stein, Switzerland
Email:	<a href="mailto:ylber.qusaj@rezonanca-rks.com">ylber.qusaj@rezonanca-rks.com</a> ; <a href="mailto:ylberjet@hotmail.com">ylberjet@hotmail.com</a> ;
Tel:	+383 44 203 549
Mob:	+41 78 800 67 51

## II. Education and training

### Undergraduate and Master Study:

Institution:	University of Tetovo, Faculty of Pharmacy, Tetovo, Macedonia
Degree Date:	01.Nov.2007
Degree :	Study of pharmacy and graduate as pharmacist
Title of Master Thesis :	"Modificated synthesis of Paracetamol"

### Postgraduate Study:

#### PhD Study:

Institution:	University of Strasbourg, Pharmacy Biogalenique, Strasbourg, France
Degree Date:	01.February 2013
Degree / Doctorate :	"Docteur de Pharmacie Biogalènique" PhD
Title of PhD Thesis :	Optimization and investigation of new Echinacea Tablets with a "Basis granulate" technology

### Training:

Institution:	Novartis Pharma AG, Stein, Switzerland
Degree Date:	July 2016

Training Course :	Train the Trainer
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### III. Preview academic experience:

1	Chronology of gaining academic titles	Year	University	Faculty	Department
a	Junior Assistant	2009-2010	University of Basel	Faculty of Pharmacy	Department of Pharmaceutical Sciences
f	Prof. as.	Oct.2020-actual	KSHM- "REZONANCA	Faculty of Pharmacy	

### IV. Subject/s in which you are involved as teaching

No.	Study Program:	Subject/s
1.	Pharmacy	Advanced Manufacturing of Pharmaceutics
2.	Pharmacy	Biopharmaceutics

### V. Research activities: Impact Factor Points for Academic Staff

#### V.A. The data for publications/Citations

No.	Author, title, paper, year, volume, number, pages	"Impact factor" points	Without "Impact factor"	Citation of your publication: Journal, Volum, Number, pages
1	Qusaj, Y.; Leng, A.; Alshihabi, F.; Krasniqi, B.; Vandamme, T. Development Strategies for Herbal Products Reducing the Influence of Natural Variance in Dry Mass on Tableting Properties and Tablet Characteristics. Pharmaceutics 2012, 4, 501 – 516.	4.58		MDPI and ACS Style , <a href="https://doi.org/10.3390/pharmaceutics4040501">https://doi.org/10.3390/pharmaceutics4040501</a> AMA Style: <a href="https://doi.org/10.3390/pharmaceutics4040501">https://doi.org/10.3390/pharmaceutics4040501</a> Chicago/Turabian Style; <a href="https://doi.org/10.3390/pharmaceutics4040501">https://doi.org/10.3390/pharmaceutics4040501</a>
2	Qusaj, Y.; Alshihabi, F.; Leng, A.; Krasniqi, B.; Tobler, M.; Vandamme, T. Development strategies for herbal products reducing the influence of natural variance in dry mass on tableting properties and tablet characteristics. The 2nd Electron. Conf. Pharm. Sci., 1 – 31 May 2012; Sciforum Electronic Conferences Series, 2012.		yes	
	TOTAL:			

### V.C. Presentations/Participation in Conferences, Congresses, symposiums, etc.

No.	Author, title, scientific meeting, abstracts book page	Oral present.	Poster present.	Participation
1	PHARMACEUTICAL CONFERENCE VI "TOGETHER FOR PHARMACEUTICALS" University of Tirana, "SINGLE USE SYSTEMS IN DRUG PRODUCT MANUFACTURING AND THEIR IMPACT ON OPERATIONAL TECHNOLOGY" Tirana, Albania	<input checked="" type="checkbox"/>		05.11.2022
1	Global Conference on Cleaning Validation, Virtual, RASUS global event "Methods and Implementations to increase the Quality of Manufacturing Production" produced by rasusevents.com	<input checked="" type="checkbox"/>		29.11.2021
1	University of Tirana, "Understanding Container Closure Integrity Testing for parenteral vials and the challenges for the pharmaceutical industry" Tirana, Albania	<input checked="" type="checkbox"/>		31.03.2018
2	Kosovo chamber of Pharmacist, "USP <1207> and FDA guidelines, on Container Closure Integrity Testing for parenteral vials and the challenges for the pharmaceutical industry" Prizren, Kosovo	<input checked="" type="checkbox"/>		04.07.2017
3	Bioforce AG, "Optimization and investigation of new Echinacea Tablets with a "Basis granulate" technology, Roggwil (TG) Switzerland	<input checked="" type="checkbox"/>		12.12.2012
4	International Pharmaceutical Conference, presentation "Development strategies for herbal products reducing the influence of natural variance in dry mass on tableting properties and tablet characteristics" Hotel Emerald, Pristina, Kosovo	<input checked="" type="checkbox"/>		22.09.2012
5	University of Strasbourg, mi-parcours, presentation "Optimization and investigation of new Echinacea tablets with a "Basis granulate" technology, Faculty of Pharmacy, Strasbourg, France	<input checked="" type="checkbox"/>		19.06.2012
6.	University of Basel, "Echinacea new formulation and their critical control point in the formulation process" Faculty of Pharmacy, Basel, Switzerland	<input checked="" type="checkbox"/>		08.02.2010
7	Bioforce AG, " presenting the dissertation goal, new ideas and the problem statements with the current formulation Echinacea tablets" Roggwil (TG) Switzerland	<input checked="" type="checkbox"/>		21.10.2009

### V.D. Scientific Interests:

Topic:	Container Closure Integrity Testing, Quality by design in Pharmaceuticals, Unique identifier in drug product
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## VI. Working Experiences:

Institution and location:	<b>Drug Product Supply, Lonza AG, Stein AG, Switzerland</b>
Period:	<b>08/2019-current</b>
Position :	<b>MSAT Expert drug product</b>
Description :	Manufacturing leader / clinical manufacturing of parenteral dosage forms - Transfer and manufacturing of clinical and commercial drug product batches from customer to Lonza Stein
Institution and location:	<b>Steriles PU Pilot Plant, Novartis Pharma Stein AG, Stein AG, Switzerland</b>
Period:	<b>12/2015 – 07/2019</b>
Position :	<b>Senior Pilot Plant Manager (Fellow)</b>
Description :	<ul style="list-style-type: none"> <li>- Manufacturing leader / clinical manufacturing of topical, oral solution and parenteral / depot dosage forms</li> <li>- OpEX SPoC for Pilot Plant: process alignment between Stein steriles and Pilot plant (including SOPs alignment)</li> <li>- Lead and manage all project/network activities and apply scientific/technical expertise to address complex R&amp;D issues for the preparation and timely delivery of drug products (DP), processes and procedures; coach team members, participate in teams and contribute to overall BTDM strategies and goals.</li> <li>- Manufacturing innovations, process development and process optimization, transfer from lab to pilot and pilot to commercial sites</li> <li>- Responsible for organizing, running and follow up External and Internal Audit for Pilot Plant Steriles Stein (FURP-AQWA A activities)</li> </ul>
Institution and location:	<b>PU Actives (Highly active substances, Oncology product), Novartis Pharma Stein AG, Stein AG, Switzerland</b>
Period:	<b>05/2013 – 11/2015</b>
Position :	<b>Process Expert drug product manufacturing</b>
Description :	<ul style="list-style-type: none"> <li>- Provide front line expert support for all process-specific issues to production within one or more production steps, to ensure execution of processes on-time, continuously improving in quality and efficiency, performed in compliance to cGMPs, SOPs and applicable guidelines and normatives</li> <li>- Review and assure that validation protocols and report are technically correct.</li> <li>- Ensure that all critical and significant parameters are within written Instruction (i.e. Master Batch Record, Validation Plan), sufficient and appropriate for the product.</li> <li>- Lead product and process related investigations and deviations including complaints, Out Of Expectation, Out Of Specification.</li> <li>- Use scientific and statistical knowledge to analyze data to provide process understanding, and to identify root causes of product and process failures.</li> </ul>

Institution and location:	<b>Research Project with University of Strasbourg and University of Basel at the Bioforce company Roggwil TG, Switzerland</b>
Period:	<b>09/2008-12/2012</b>
Position :	<b>PhD Student</b>
Description :	<ul style="list-style-type: none"> <li>- Standardization of the herbal extract (concentrate) in fabrication scale</li> <li>- Execution of the experiments in the Scale-up and fabrication scale</li> <li>- Writing two publication in the field of the optimization of the herbal plant extract</li> <li>- Assistant in the practical training of solid dosage forms</li> </ul> University Basel, Switzerland

## VII. Other Experiences:

A.	Managing experiences, projects managing, etc.	Year	University	Faculty	Department
1	Project leader in implementation of material flow in Novartis AG Switzerland and Lonza Group Switzerland	2017-2020	Novartis AG Switzerland		

## VIII. Additional informations:

Organizational skills and competences:	Price from Novartis AG Switzerland company: Stein Steriles "EdelStein Rubin" September 2018.		
Computer skills and competences:	<ul style="list-style-type: none"> <li>- Very good user knowledge of the MS Office programs Excel, Word, Outlook and PowerPoint</li> <li>- Good user knowledge in software: Optimize Global, Mini Tab, MODE, Stavex</li> <li>- Very good practical knowledge of ERP system (super user), such as SAP, TMS and with the reference management with the software Endnote</li> </ul>		
Language skills: (1 to 5: 1 lowest - 5 fluent)			
Language	Speaking	Writing	Reading
English	5	5	5
German	5	5	5
Albanian	5	5	5

Name and surname:

Ylber Qusaj

Signature *Ylber Qusaj*

Pristina, dt. 27.02.2023