SUMMARY OF PROFESSIONAL EXPERIENCE

(Nadeem Hussain Alamgir)

I have worked for >30 years in Healthcare industry where I am respected because of my professional capabilities in sales/marketing and in understanding and delivering regulatory excellence by both Industry and Regulatory Authority. I have traveled extensively and learned many dimensions by attending international conferences especially on Medical Device Regulations.

Currently I am a consultant to "Pharma Bureau" which is a sub-committee of "Overseas Investors Chamber of Commerce and Industry" representing the research based Multinational pharmaceutical companies in Pakistan. I am also representing Pharma Bureau in different statutory Bodies constituted under Drugs Act 1976 as an Observer.

I have Started my >30 years carrier as Professional Sales Representative in Merck Sharp & Dohme Pakistan Ltd in 1985.durig my professional carrier I had worked for Akhai Pharmaceutical (Pvt) Ltd from 1996 to 2003, Roche Pakistan Ltd. (a subsidiary of F Hoffmann La-Roche Switzerland) from 2003 to 2008 and from 2008 December to December 2010 worked as the first ever Regulatory Affairs (HoD) in Johnson & Johnson Pakistan Ltd (a Medical Device Company). Than HoD in Regulatory affairs department in Reckitt Benckiser an FMCG company. Recently been working as Director Regulatory Affairs at Martin Dow Pharmaceutical Ltd. Now I am working as CEO/Director at RA Consultants (SMC-PVT) Ltd, a company providing services to healthcare industry in the field of Regulatory Affairs & Capacity Building.

I have numerous achievements to my credit in sales marketing and Regulatory Affairs. I am the primary Industry Representative in Asian Harmonization Working Party. Remained part of committee for pharmaceutical sector reforms and was instrumental in amendments to Drug Regulations in 2002. I worked on establishment of Drug Regulator Authority of Pakistan (DRAP) and been a part of development of Relevant Act before the DRAP Act was approved by the Parliament and enacted in September 2012. After establishment of DRAP I worked for Medical Device Legislation with Drug Regulatory Authority of Pakistan as member of committee constituted for the said purpose. I also help prepare Contract Manufacturing Policy with DRAP in line with aspirations of both Industry and DRAP. Member of Committee constituted by Central Licensing Board for amendments in Drugs (Licensing, Registration & Advertisement) Rules 1976.

While working as Regulatory Affairs Professional for different companies I successfully resolved long standing issues like 35 years old dispute between Johnson & Johnson and the regulatory Authority in Pakistan. I have worked with Quality and

Production departments for improvement of compliance to cGMP and Regulatory Laws. I was trained as a trainer for implementing change control procedure developed by Reckitt Benckiser Global after Quality Control disasters in South Africa & Pakistan.

I Initiated and concluded bid for Pakistan's membership in AHWP (Asian Harmonization Working Party) after 15 years of the existence of the organization. I am also been giving lectures on medical devices at Pharmacy Department of Hamadard University Campus at Islamabad Pakistan on the request of the University Administration.

I have attended many conferences and trainings enhancing my capabilities. I worked for and also been a trainer on different aspects including change control at Reckitt Benckiser.

My Detailed CV is attached herewith for review.

CURRICULUM VITAE

Name:	Nadeem Hussain Alamgir
Fathers Name:	Rehmat Ali
Marital Status:	Married
D.O.B:	17 February 1962
Postal Address:	House No: 347 Street No 17, Block-D PWD Housing Society (Lohi Bher) Islamabad (Pakistan)
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PROFILE

Professional Experience (>30 Years)

(Current) CEO/Director at RA Consultant (SMC-Pvt) Limited. In my personal capacity I am a consultant to Pharma Bureau a sub-committee of Overseas Investors Chamber of Commerce and industry, representing the research based multinational pharmaceutical companies. I am Project Coordinator (United States Pharmacopeia) for a USAID Project in Pakistan. I am also providing consultancy services to many other companies.

(June 2012 – September 2013) Director Regulatory Affairs at Martin Dow Pharmaceutical Ltd. Pakistan. Responsible for all Regulatory and Government affairs at national and international Level.

(January 1, 2012 – April 2012) Reckitt Benckiser send me on secondment to UAE Regional office to help the Regional Quality to achieve their assigned objectives related to training of Regional Manufacturing Units on Change Control Management and analyses and development of Regional Business SOP.

(January 1, 2011-December 2011) Joined Reckitt Benckiser Pakistan to Head the Regulatory Affairs Department as Regulatory Affairs Manager. The company changed the location of appointment from Karachi to Rawalpindi to facilitate my Joining.

(December 2008- December 2010) Joined Johnson & Johnson Pakistan as Manager Government and Regulatory Affairs based at Islamabad.(Head of Department) I was the First Regulatory Affairs Manager in a Medical Devices Company in Pakistan. From Jan 2010 I was appointed as Regulatory and Government Affairs Manager at

the Region with the assignment to assist Johnson & Johnson Pakistan in the issues related to Medical Devices Regulations.

(July 2003 – November 2008) Joined Roche Pakistan Limited in July 2003 as Regulatory Manager based at Islamabad and promoted to Regulatory Affairs Manager in January 2006.

(January 1996 – July 2003) Joined Akhai Pharmaceuticals Regional Manager North Zone with an objective to supervise the existing product groups and launch new product groups in the region. Management of Akhai Pharmaceutical gave me an additional responsibility for regulatory affairs. After evaluating my performance the management promoted me as Regulatory Affairs Manager based at Islamabad with a staff of three persons. I was transferred to Head office as Head of Regulatory Affairs and Head of Administration and International Affairs.

(September 1985 – January 1996) Joined Merck Sharp & Dohme as Trainee Professional Sales Representative than in January 1990 I was promoted as Senior Professional Sales Representative and after evaluation of my performance I was promoted as Field Manager (Latter Regional Manager) for Special Promotion Group in North Zone.

ACHIEVEMENTS

REGULATORY AFFAIRS

INDEPENDENT CONSULTANT
I was part of development of Drug Regulatory Authority of Pakistan Bill 2012.

Developed Medical Device regulations as a member of Committee constituted by Government of Pakistan.

Worked and Develop Contract Manufacturing Policy with Drug Regulatory Authority of Pakistan.

Member of Committee constituted by Central Licensing Board for amendments in Drugs (Licensing, Registration & Advertisement) Rules 1976.

Working with Drug Regulatory Authority on implementation of cGMP standards as an Observer in Drug Registration Board & Central Licensing Board.

Project Coordinator to a USAID Project in Pakistan for United States Pharmacopeia Convention related to Capacity Building of DRAP and Industry.

ECKITT BENCKISER PAKISTAN LTD.
2011was a very difficult year for industry as the Ministry of Health was under Devolution and the regulatory system was halted after June 30, 2011 due to non-existence of Drug Control Administration at Federal Level. Despite of these difficulties I was able to achieve the following,

- Renewal of 39 Licenses of Drugs.

- Renewal of Drug Manufacturing License that was on hold since 2010 on technical grounds.

- Price increase of 28% for Gaviscon (240ml Bottle)

- Price Increase of 6.5% for Gaviscon Advance (120ml Bottle)

- Approval of Revamping Plan of Disprin Production Area for Mauripur Factory.

- Legal Case of violation of Drugs Act 1976 were single handedly defended and favorable decisions were obtained from first tier of prosecution courts (Quality Control Board under Drugs Act 1976)

    - Supply of Drugs under improper conditions (Rawalpindi)
    - Sale of Spurious, unregistered and misbranded Dettol MPC (Karachi)
    - Sale of Substandard Disprin Tablets (A Suo Motto Action by Peshawar High Court for supply of substandard drugs/Medicines to Mardan Jail)
    - Successful Response to numerous allegation of Violation of Drug Act 1976 by different regulatory authorities.

- On Time delivery of GRAIS data.

- Development of Short Expiry Products Sale & Return Policy.

- Training of Factory Personal (Manufacturing. QA. SSG, Supply) on cGMP compliance under Drugs Act 1976.

- Training of Field Force on Regulatory Compliance.

- Trainer for Pakistan and Regional Regulatory Affairs on Change Control & Cross Functional Change Control.

- Analyzed available SOP's for business and update/developed SOP for region and Pakistan business.

- Member of Global Regulatory Excellence (RegEx) Project team for development of New Business Model of RB.

JOHNSON & JOHNSON PAKISTAN (PVT) LTD

- 30% Price increase of surgical sutures manufactured locally for two consecutive years which was unprecedented in the history.

- Member of committee working on Draft Medical Devices Act 2009. Working on different projects of JNJ. Realizing my potential and expertise management has appointed me as Brand Integrity Lead for Pakistan.

- Declared Best Employee of year in very first year of service with J&J.

- Developed Advertisement and Copy Approval SOP and implemented in the company for first time in the history of J&J Pakistan.

- Developed JD for Brand Integrity Lead.

- Developed Brand Integrity SOP for Pakistan for the first time.

- Solved a 35 year old dispute regarding registration of surgical sutures with the Ministry of Health in the favor of J&J.

ROCHE PAKISTAN LIMITED

- Registration of 22 innovative products since joining Roche Pakistan (every Drug Applied since joining along with few pending cases) numerous changes in site of manufacturer change of source and change of formulation of Pegasys in a record time of 2 weeks resulting in a cash reward by the Managing Director.

AKHAI PHARMACEUTICAL

- Registration of 53 products in 4 years after promotion as Regulatory Affairs Manager. Numerous site changes and change of name of products.

- Almost Single handedly won two court cases at Drug Court Peshawar and High Court Sindh. I prepared both the cases for the lawyers to present in court and in both the occasions the hired advocate was new to the subject.

- Developed SOP for handling of Anesthesia Dispensers for Isoflurane and also developed and implemented Contract for use with Hospitals where the dispensers were to be installed.

- Developed Administration/HR Policies for Head office including SOP for attendance of office by the field force and the office employees.

- Developed finance control SOP

- Developed and Implemented Appraisal System for Field Force based on the Principal of Management by Objective (MBO).

- Developed Contract for Toll Manufacturing of Companies products by a third party.

DIRECT SELLING

AKHAI PHARMACEUTICAL

- Increases the sales by 100% in a period of 6 years in Akhai Pharmaceutical while looking after regulatory affairs as an additional responsibility.

- Introduced three new product categories (Division) including Health care products division, Sutures Division and second antibiotic group.

- Developed marketing strategies for new groups hired and trained personals for marketing of the new product divisions resulting successful launch and subsequent growth of all the three divisions.

MERCK SHARP & DOHME

- Achieved 158% target of Tinam (MSD) in first complete year of launch while looking after the biggest area allocated for the promotion of Tinam.

- Always achieved the sales target as a representative and than as a Field Manager while looking after a complete zone. My highest achievement was in 1995 when I exceeded the target of North Zone by 58% with achievement of the target of each and every product.

- Won the membership of Elite Club twice in 1986 and 1990 for my performance and achievement in sales.

- Because of extra ordinary sales performance apart from incentives throughout my carrier with MSD, I was awarded the gold medal in 1990 by the Managing Director of MSD.

OTHER ACHIEVEMENTS/EXPERIENCE

- Member of the committee created by the cabinet under Mr.Razak Dawood than Minister of Industries and Commerce for reform of drug sector.

- Attached as resource consultant by the consultant of Ministry of Industries hired for proposing amendments in Drugs Act 1976 on the instructions of Minister of Industries.

- Developed proposals for the amendment in Drugs Act 1976 and presented to the Government through the consultant resulting in promulgation of Drugs Act 1976 Amendment Ordinance in 2002.

- Prepared a report on problems faced by Pharmaceutical Industry in Pakistan and was presented to the government resulting in formation of above mentioned committee.

- Help expert Advisory cell of Ministry of Industries in preparation of report for reforms in Pharmaceutical industry.

- Primary Industry Primary Member at Asian Harmonization Working Party (AHWP) from Pakistan.(AHWP is a group of Asian Countries working for harmonization of Medical Devices Laws in the Region.)

- Nominated Board Member of Asian Harmonization Services Limited.

- Instrumental in Getting Membership of Pakistan in Asian Harmonization Working Party.

- Prepared a report for a Drug Regulation Structure in Pakistan post 18th Constitutional Amendment and provided to all the Chief Ministers and Prime Minister of Pakistan.

- Developed as Trainer for Change Control Management in Reckitt Benckiser in order to infuse new spirit in pharmaceutical quality control.

- Speaker on Medical Devices Management at Hamdard University (Islamabad Campus) Pharmacy Department.

- Member of committee for development of Medical Device & Medicated Cosmetics regulation of Drug Regulatory Authority of Pakistan. (Main contributor on Medical Device Rules as a specialist on the subject). I have prepared the Rules for Medical Devices Regulations to be implemented by DRAP after approval from Policy Board.

- Worked with DRAP for development of Contract Manufacturing policy in line with aspiration of Pharmaceutical Industry and DRAP.

PERSONAL CAPABILITIES

- Sufficient experience in administration.

- Sufficient experience in handling sales force and marketing activities.

- Sufficient experience in analyzing and preparing development plans for marketing of products.

- Experience in developing controlling tools for field force and performance evaluation.

- Arranging and delivering Training on technical issues like cGMP, Change Control and different SOP like Pharmacovigilance, Advertisement and Copy Approval etc.

- Sufficient experience in independent handling of regulatory/legal affairs.

- Well versed in preparation of Registration dossier and correspondence with the Government.

Conference Attended

- Biosimilar workshop By F.Hofman La Roche Dubai Jan 2008 .

- Asian Harmonization Working Party 14th Annual Conference Hong Kong November 2009.(Where I bid for membership of Pakistan after 14 years of existence of this group. This resulted in the ultimate membership of Pakistan in Riyadh SA in 2012)

- Regional Regulatory & Medical Affairs Conference By Johnson & Johnson Singapore November 2009

- Asian Harmonization Working Party Technical Committee Meeting Taiwan July 2010 (where I was invited by the Government of Taiwan as Memberof AHWP).

- Regional Conference of Johnson & Johnson Sharm al Shiekh (Egypt) January 2010

- Regional Conference Market Access Group J&J Cairo (Egypt) May 2010

- PASIAN Regional Conference Johnson & Johnson New Zealand March 2012

- Global Regulatory Affairs Conference Johnson & Johnson Ljubljana (Slovenia) November 2012.(Where I conducted a workshop on Drug & Devices Regulation in Pakistan)

- Asian Harmonization Working Party Conference 15th Annual Meeting Riyadh Saudi Arabia November 2010 (Participated as Primary Member for Pakistan Industry and was a co presenter of Pakistan Report with members of Ministry of Health Pakistan at this occasion Pakistan's Members ship was approval for which I worked since 2009)

- Regional Regulatory & Medical Affairs Conference by Reckitt Benckiser March 2011.

- Global Regulatory Affairs Conference by Reckitt Benckiser Berlin (Germany) June 2011.

- Regional Regulatory & Medical Affairs Conference by Reckitt Benckiser Dubai March 2012 (Where I held a training on Change Control for Regulatory & Medical Affairs team)

<u>Special Strengths</u>

- Understanding of Drug Law and Rules

- Strategic Planning

- Team Building

- Marketing Planning

- Developed company policies and systems

- Development of Professional relations with government functionaries.

- Training

- Organizing seminars and Conference

EDUCATION

ACADEMIC

Bachelor of Science in Zoology, Chemistry and Applied Psychology 1985.

PROFESSIONAL COURSES

Merck Sharp &Dohme	High Impact Leadership
Merck Sharp &Dohme	Coaching and Counseling
Merck Sharp &Dohme	Group Communication Skills
Merck Sharp &Dohme	Performance planning and objective setting
Merck Sharp &Dohme	Interviewing Skills
Merck Sharp &Dohme	Professional Communication Skills (I & II)
Merck Sharp &Dohme	Professional Communication Workshop
Merck Sharp &Dohme	Prescribing Continuum
SIPS Jordan	Medical Device Regulatory Affairs Workshop.
Reckitt Benckiser	Change Control Management
Reckitt Benckiser	Business Management System
Other Interests	Working for Implementation of international standards in Pharmaceutical Manufacturing in Pakistan by motivating DRAP and Industry as an Observer member in DRUG Registration Board and Central Licensing Board. Reading Books, Understanding Law