CONNECTED VIA PharmaCompass.com CONNECTED VIA

Aizant Drug Research Solutions

Integrated Drug Development Solutions

Flow of presentation

- Introduction
- Business verticals
  - CDO Capabilities
  - CMO Capabilities
  - Out-licensing Capabilities
  - CRO Capabilities
- Support functions
- Advantage
- Contacts

Vision & Mission

VISION

- To be a global leader for science based integrated drug development solutions

MISSION

- Pursuit of excellence through science and technology
- Agile team with open communication and honoring deliverables
- Environmentally and socially responsible research

VALUES

- **I**nnovation
- **P**eople
- **L**earning
- **Q**uality

Name and Logo

"Aizant" is derived from the name "Aizan", Caribbean goddess of healing and "T" was added for Technology

Arrow head represents GROWTH

Bird in flight signifies FREEDOM

Four circular walls – four values Innovation, People, Learning and Quality

Blue arc – our POSITIVE attitude

Our logo – GLOBAL experience and standards

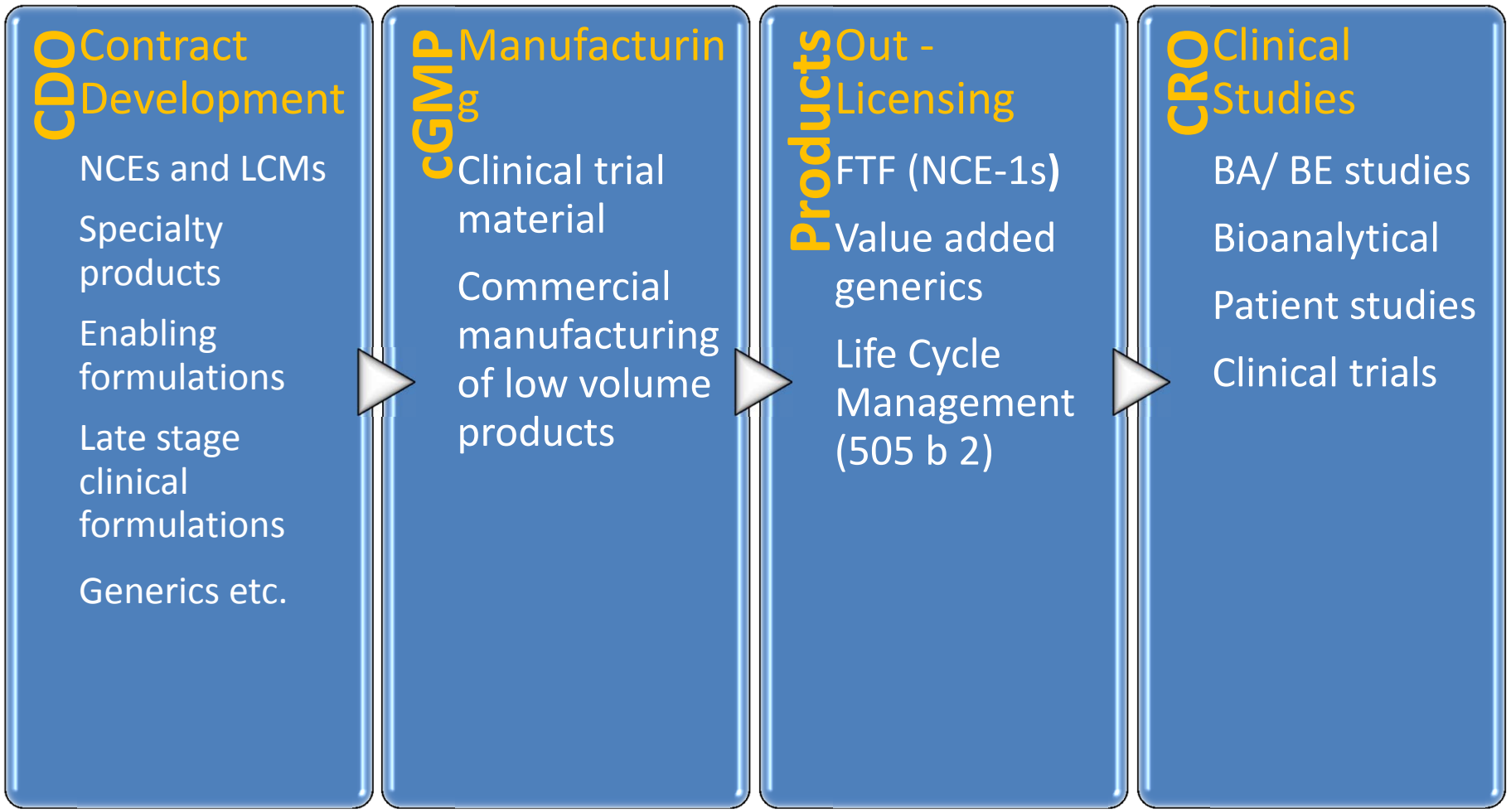
Milestones

2005	• Aizant incorporated
2008	• Formulation R&D and clinical operations started
2009	• cGMP facility commissioned
Apr 10	• Clinical facility audited by US FDA with **NO 483s**
May 10	• Diagnostics laboratory accredited by NABL
Aug 10	• Clinical facility was approved by Brazilian ANVISA
Oct 11	• Clinical facility approved by WHO
Dec 11	• Clinical facility approved by Turkey MoH
Jan 12	• Successful US FDA NDA approval for product developed at Aizant
Feb 13	• Started construction of commercial manufacturing facility
Jun 13	• BA/BE facility audited by US FDA with zero 483s
Oct 13	• BA/BE facility audited by ANSM (France)
Jun 14	• First ANDA Filed
Sep 14	• First FTF filed with US FDA
Oct 14	• WHO approval for manufacturing facility

Flow of presentation

- Introduction
- Business verticals
  - CDO Capabilities
  - CMO Capabilities
  - Out-licensing Capabilities
  - CRO Capabilities
- Support functions
- Advantage
- Contacts

Business Verticals



CDO – Infrastructure

- State of the art pharmaceutical development laboratories spread over 40,000 sq. feet
- Modern equipments and instruments in formulation and analytical laboratories in tune with latest technology
- ~ 80,000 sq ft open space for scaling up any operations within short time
- Development capabilities for:
  - Oral dosage forms (solid/ liquid)
  - Novel Drug Delivery Systems
    - Controlled release/ sustained release/ extended/ modified release dosage forms
    - Multiparticulate systems
    - Gastro-retentive system
  - Topical dosage forms
  - Parenteral dosage forms
    - Lyophilisation
    - Depot formulation
    - Liquid injections
  - Ophthalmic dosage forms

Quality

- Quality is by design and not an after thought
- QbD is fundamental to our operations
  - Target the product profile (TPP)
  - Determine the critical quality attributes (CQAs)
  - Link input material attributes and process parameters to CQAs and perform risk assessment
  - Develop a design space
  - Design and implement a control strategy
  - Manage product lifecycle, including continual improvement

CDO - Services

Preformulation	Formulation Development	Analytical Development	Other Services
• Reverse engineering • Thermal analysis • Dynamic vapor sorption • Particle size analyser • Viscosity measurements • Solubility studies • Dissolution studies (Type I, II, III, IV) • XRPD, SEM, Hot stage microscopy*	• Dry blending • High shear granulation • Fluid bed granulation • Roller compaction • Extrusion spheronisation • Wurster coating • Spray drying • Micronization • Pan Coating • Encapsulation • Injectable lyophilisation • Injectable depot formulation	• Method development • Method validation • Method qualification • Method transfers • Stability studies including zone IV studies • Chiral analysis • Microscopy	• Scale-up and technology transfer • Stand alone stability studies • Product registration and regulatory support • Clinical support • Separate facility for potent substances

Differentiating technologies offered

- Nanotechnology
  - Liposomes
  - Nanoparticles
  - Dendrimers
  - Nanofibers
  - Polymeric micelles
- Hot Melt Extrusion (HME)
  - Bioavailability enhancement
  - Stability enhancement
  - Controlled release formulations
  - Product life cycle extension
  - Taste masking and Pediatric dosage form
  - Cost reduction

Differentiating technologies offered

- Potent substances
  - Dedicated Lab of 500 sq. ft area for the Development of Oncology Products
  - Isolator for handling highly toxic (upto Category IV) molecules
  - PAPR (Power Air Purifying Respirator) for additional safety
  - Capability of developing Generic/ NCE Onco products as well as Onco Injectables for 505(b)2 filling.
- Parenteral development
  - Liquid & suspension for injection
  - Lyophilized powder for injection
  - Long acting injectable
  - Ophthalmic solutions & suspensions
  - Liposomes
- Spray drying

cGMP – Infrastructure

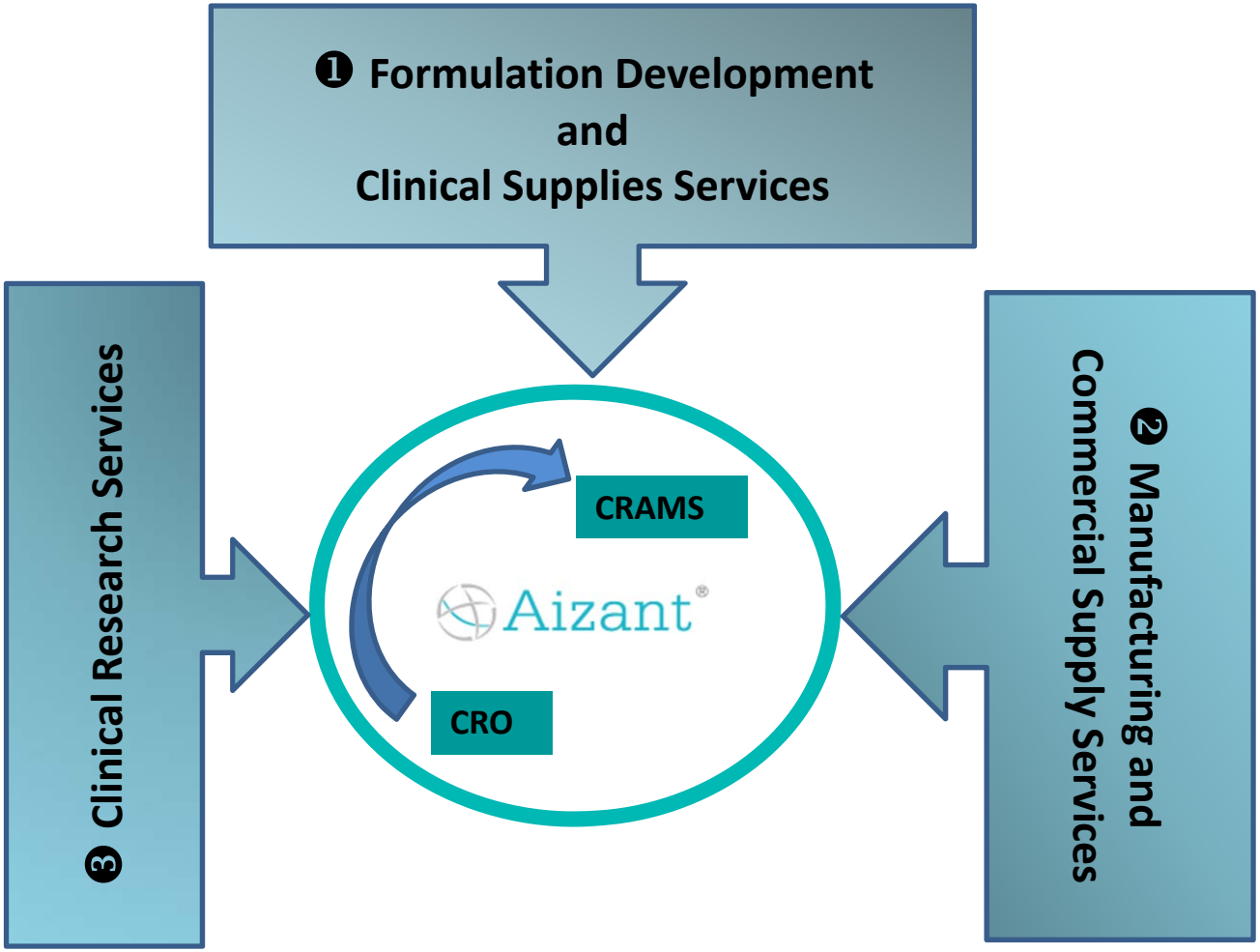
- About 10,000 sq. feet cGMP area for low volume commercial supplies, exhibit, scale up and clinical batch manufacturing
- Approved by WHO
- Filed three ANDAs and invited EU agency for regulatory audit.
- Dedicated AHUs
- Flexibility of manufacturing batches upto 80kgs
- Power back to ensure smooth operations
- Ensures OSHA compliance and other industry legislations
- Process train for solid orals:
  - Up to 15 kg
  - Up to 100 kg

cGMP - Services

Scale up	Clinical trial material	Analytics	Other Services
• Scale up of formulation development products • Manufacturing batches for regulatory submissions • Commercial manufacture • All kinds of packaging	• Investigational drug product • Placebo • Encapsulation of tablets, multiparticulate, capsules and other solid dosage forms • Comparator manufacturing • Clinical packaging, blinding, randomization	• Testing and release of finished goods • Cleaning validation/ process validation • Microbiology • Stand alone stability testing	• Regulatory support • eCTD compilation

cGMP Expansion

……..Transition from CRO to CRAMS of finished product



Expansion – Layout (With Manufacturing)

Salient Features of Manufacturing Plant

- State-of-the art oral solids with capacity to produce *1-billion units* per annum for all regulated and semi-regulated markets.
- Facility is being designed to have:
  - Wet-granulation
  - Dry-granulation
  - Roller compaction
  - Direct compression
  - Multiple Unit Particulate Systems (MUPS) pelletization
  - Extrusion-Spheronization
  - Wurster-Processer
  - Hot-Melt Extrusion (HME)
  - Controlled/Delayed Release (CR/DR) Technologies
  - Unit Dose (Blisters/Strips) and Bottle packaging lines.
  - Provision for dedicated suit for handling clinical supplies and potent actives with novel technology platforms including HME, Nano, MUPS, CR/DR, etc for developing differentiated products.
- Facility is being designed to handle multiple actives and products at a time, yet complying to regulatory norms.

Products – Infrastructure

- Dedicated team for development of internal projects supported by in-house IP team for patent landscape evaluation
- Working on following category of products:
  - NCE-1/ FTF (First to File) – filed 2 FTFs
  - Salt change strategy
  - Life cycle management opportunities (505 b2)
  - Niche generics
  - Me too generics
- Business model
  - Out-licensing with commercial supplies
  - Alternate models such as co-development, technology transfer can be worked out on case to case basis

Product Portfolio

S.No.	Product	Dosage Form	Strength	RLD
1	Abiraterone	Tablets	250mg	Zytiga
2	Acetazolamide	ER Tablets	500mg	Diamox Sequel
3	Aripiprazole	Tablets/ ODT	2, 5, 10, 15, 20, 30mg 10, 15mg ODT	Abilify
4	Cefaclor	Tablets	500mg	
5	Dapsone	Tablets	25, 100mg	Dapsone (US)
6	Febuxostat	Tablets	80,120 mg	Adenuric-EU, Uloric-USA
7	Felbamate	Tablets	400, 600mg	Felbatol
8	Lamivudine	Tablets	150. 300mg	Epivir
9	Metformin XR	Tablets	1000mg	Glucophage
10	Naproxen Sodium	ER Tablets	375, 500, 750mg	Naprelan
11	Tenofovir Fumarate	Tablets	150; 200; 250; 300mg Tablets	Viread
12	Zileuton	C R Tablets	600mg	Zyflo CR

CRO – Infrastructure

- 80 bed (2 clinics) facility spread over 28,000 sq feet
- IP based cameras to virtually monitor projects
- Dedicated registration area
- Independent ethics committee/ Institutional Review Board
- In-house NABL accredited clinical diagnostics laboratory
- In-house kitchen
- Bioanalytical laboratories equipped with 10 LCMS/MS including API 5500
- Offsite storage of data for disaster recovery and business continuity
- Volunteer database
  - Male: 8000+
  - Female: 2000+
  - Access to post menopausal women database

CRO - Services

Clinical Pharmacology	Bioanalytics	PK & Biostatistics	Diagnostics
• Clinical studies for males, females and special population • BA/BE studies for global submissions • Proof of concept studies • Patient PK Studies • Food Interaction Studies • Clinical end point studies and Clinical Trials • Data Management	• Method development and validation • Method transfer of drugs in biological matrix • LCMS-MS and HPLC analysis of drugs and metabolites in biological matrix from clinical trial	• Study design • CRF review • Randomization schedule • Statistical analysis & reporting (SAS 9.2 and WinNonlin 5.2 software) • Well trained staff	•Hematology •Biochemistry •Immunology •Urine analysis •X-ray

CRO - Regulatory approvals

- **US FDA** audited facility with NO 483s
- **ANVISA** inspection successfully completed (**No major or critical observations)**
- **NABL** accreditation for clinical diagnostics
- **DCGI** inspected and approved
- **WHO** approved
- **Turkey MoH** approved
- **ANSM (France)** approved
- **ISO 9001**
- **ISO 15189**

Flow of presentation

- Introduction
- Business verticals
  - CDO Capabilities
  - CMO Capabilities
  - Out-licensing Capabilities
  - CRO Capabilities
- Support functions
- Advantage
- Contacts

Project management

- Cross functional project teams from formulation, analytical, quality and regulatory departments
- All projects teams are monitored on MS projects by an experienced project manager
- Metrics based project planning and execution
- Well defined communication systems as decided at beginning of project
- Good track record of completing projects on time

Information technology

- Data-centre with backup and recovery facility
- Offsite data storage for disaster recovery
- IP Cameras for remote virtual monitoring of projects
- Biometrics for cross-check and validation
- Well defined IT policy for security and access control
- Metrics based reporting

Flow of presentation

- Introduction
- Business verticals
  - CDO Capabilities
  - CMO Capabilities
  - Out-licensing Capabilities
  - CRO Capabilities
- Support functions
- Advantage
- Contacts

Experience

Projects

Handled over 180 + development and 400 + clinical projects since inception development projects include:

Simple IR , complex IR, Simple MR, complex MR, Combination products, LCMs, NCEs

Geography

Rich experience of working in various regulatory environment

USA, EU, LatAm, Worldwide, RoW

Clients

Versatile in working with various partners

Big Pharma,

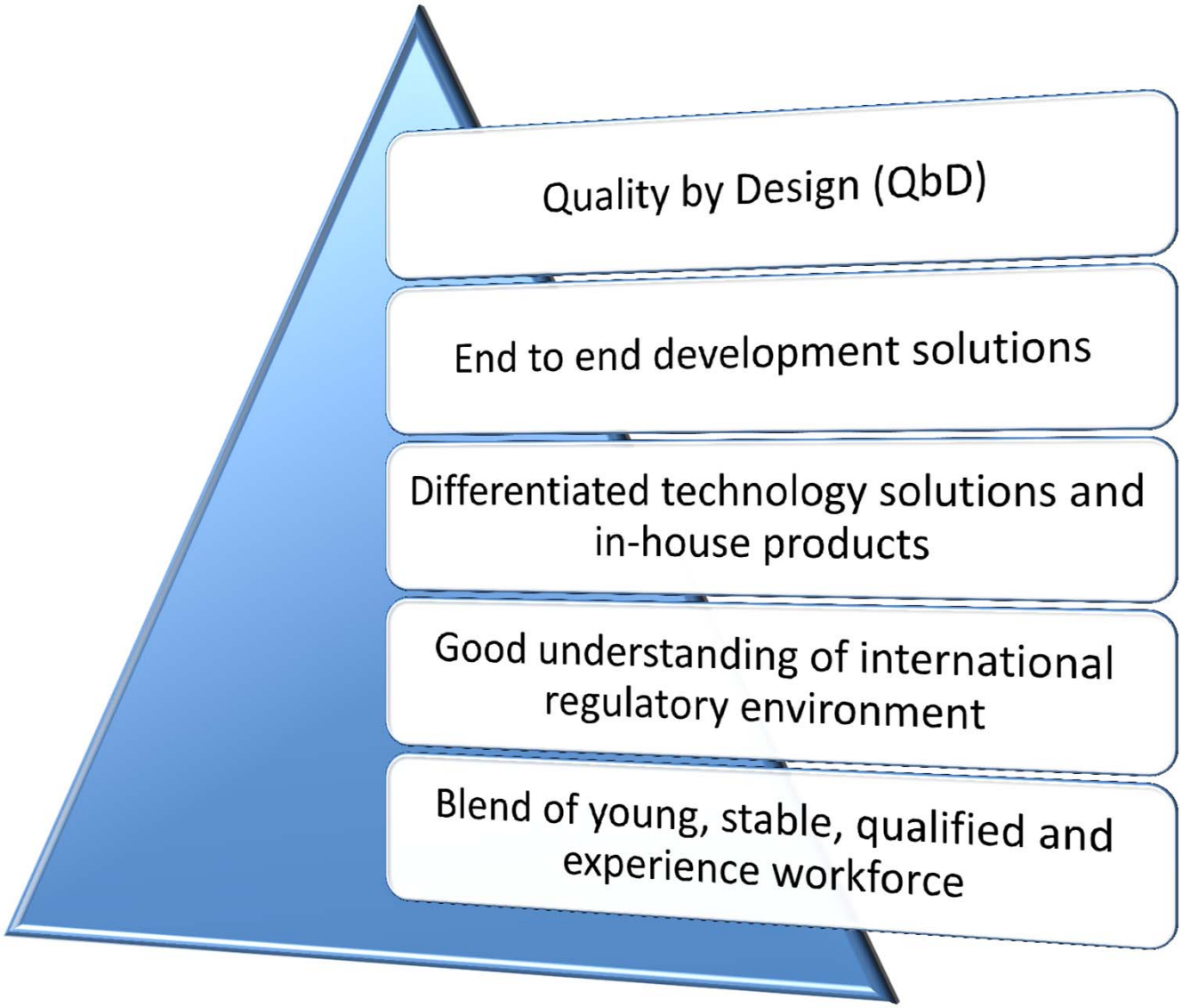
Specialty,

Generics, Indian

Generics

Total team of ~400 people between Product development, clinical development and GMP business verticals

Advantage Aizant



Contacts

Aizant Drug Research Solutions Pvt. Ltd.

Sy. No. 172 & 173, Apparel Park Road,

Dulapally, Hyderabad, India – 500014

Phone: +91 40 23792190

E-mail: praveen.s@aizant.com, Website: www.aizant.com