



Ausun Pharma

Your Reliable Strategic Partner!

Company History



2008
→
Founded
Ausun Tech

2010
→
Founded Ausun
Pharma

2012
→
First workshop
in operation

2013
→
* EU GMP
certificate

2014
→
* US FDA audit
* ISO14001
* OHSAS18001

2016
→
* J PMDA audit

2017
→
** IPO

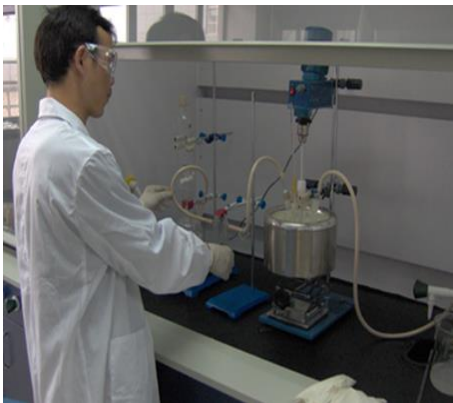
2018
→
* US FDA audit
no 483
* ISO14001
* OHSAS18001



** IPO at the Shanghai Stock-exchange on May 9, 2017



Vision & Mission



Vision of Ausun

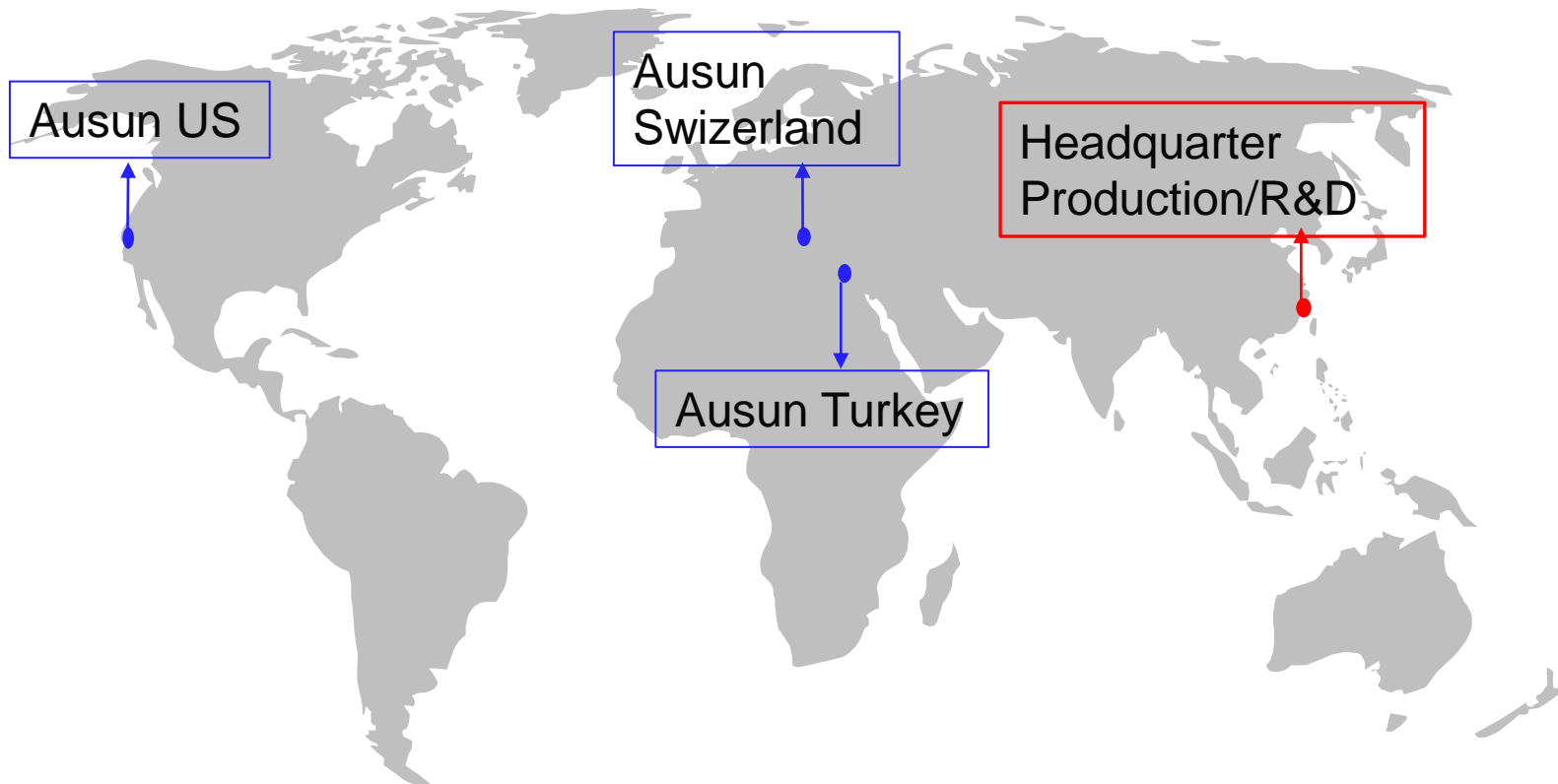
To be the global partner of high quality intermediates and API's to the Pharmaceutical Industry

Mission of Ausun

Creative Chemistry For Better Health



Ausun Global



Site Construction Plan

Phase II



- Established: **April 2010**
- Total Area: 120,000 m²
- Construction Area: 59,950 m² (Phase I)
- Green Area: 29,600 m² (Phase I)
- Total Investment: **USD 102 million**
- Phase I Investment: **USD 19 million**
- Production launched: **Dec 2011**
- Location: **Zhejiang, Linhai Zone**

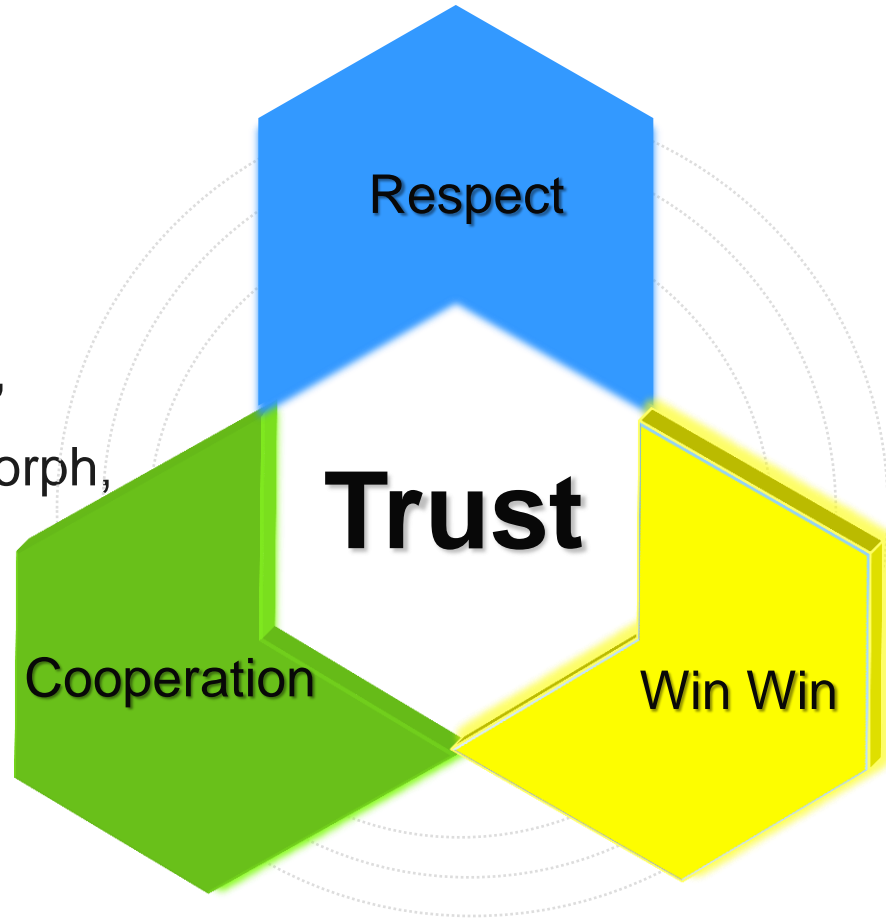
Phase I



Company Values

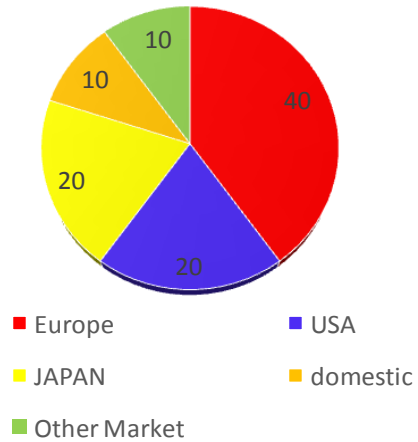
Ausun Focus:

- **Time**
- **IP**
- **Quality** (Purity, relative substance, residual solvent, foreign matter, PSD, Polymorph, Static electricity etc.)
- **Documents**
- **GMP/EHS**
- **Reliable Supply**
- **Competitive Price**

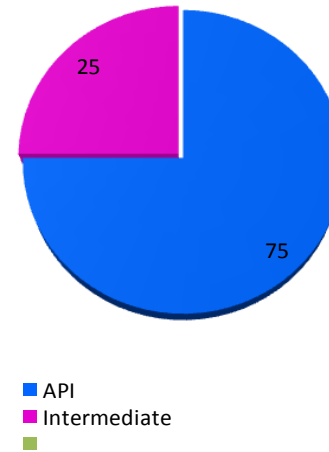


Sales Situation

Country

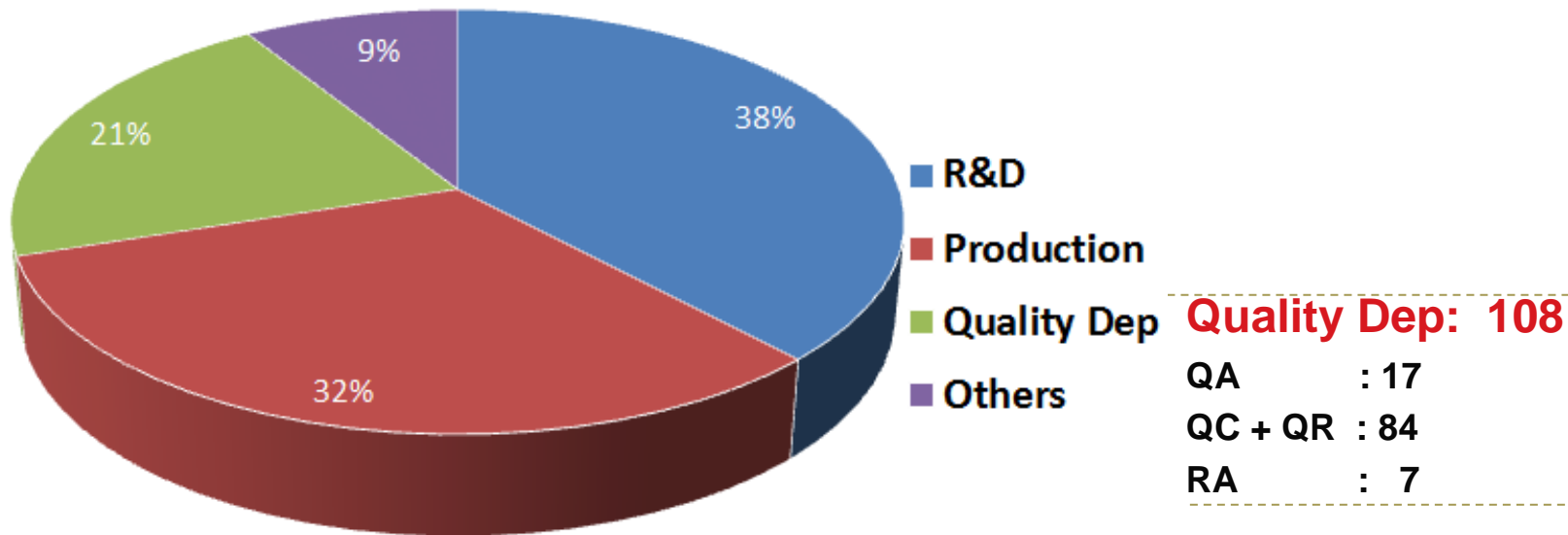


Function

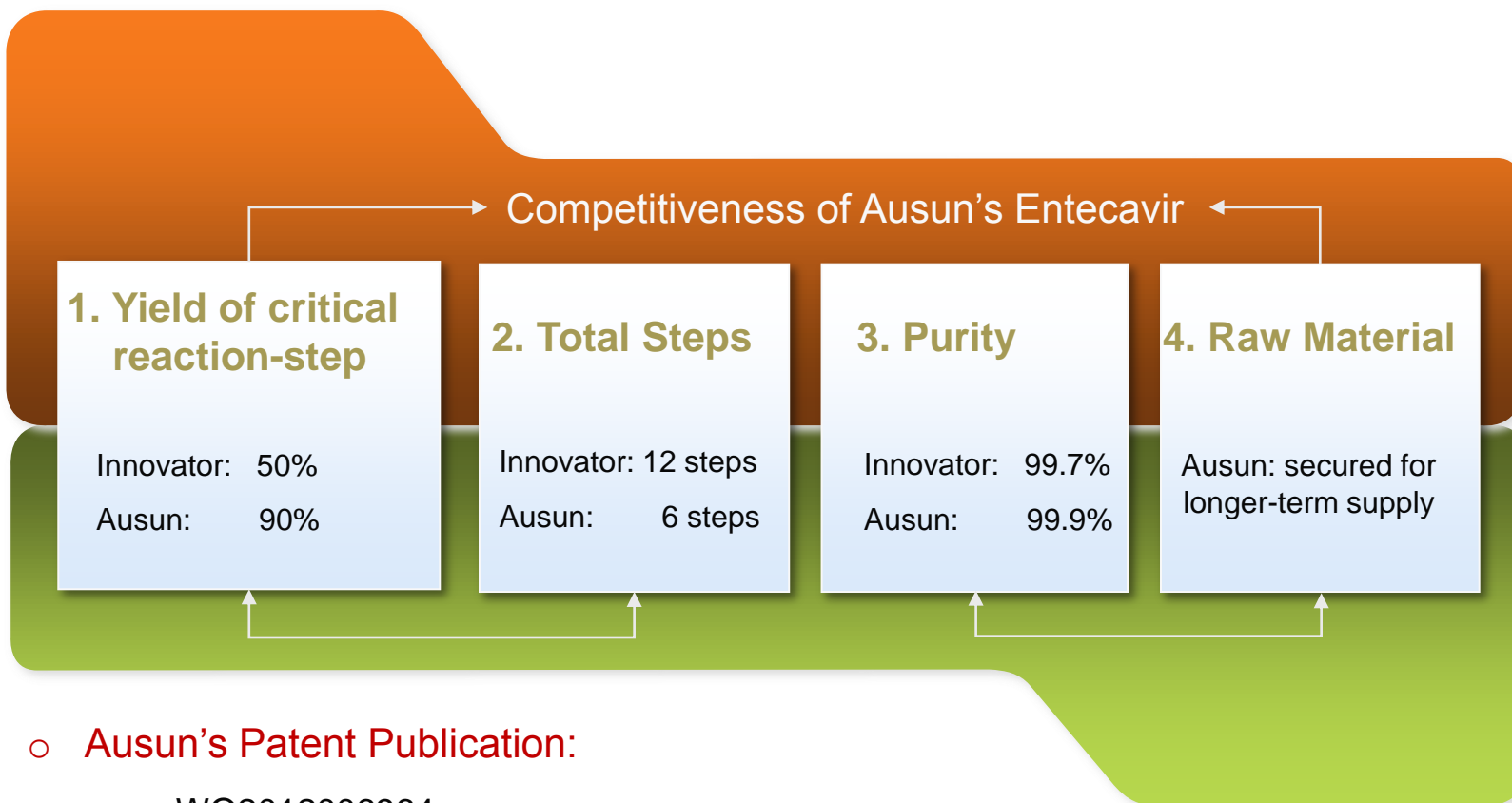


Employees

Total employees: 560



Example Innovation in Process-Development



○ Ausun's Patent Publication:

- WO2012006964
- TW99128044 , TW100121049
- CN201010230153.7, CN201110196709.x



Reactor Capacity

Workshop	Reactor size (L)	Reactor MOC	Capacity
WS 1	20 ~ 3000	GL, SS	54.5 m ³
WS 2	500 ~ 5000	GL, SS	161.5 m ³
Multi-Product WS	200 ~ 3000	GL, SS	30.3 m ³
Hydrogenation WS	100 ~ 2000	SS, Hastelloy	5.5 m ³
WS 3	500 ~ 5000	GL, SS	180.5 m ³



Major Analytical Instruments

Instrument Name	Type	Quantity
HPLC	Agilent 1200 /1260	33
GC (with Headspace)	Agilent 7890	6
GC-Mass	Agilent 7890-5977B	1
LC-Mass	Agilent 1260UHPLC+6470	1
ICP-Mass	Agilent 7900ICP-MS	1
XRD	MiniFlex 600	1
Stability Chamber	Binder KBF720/ LEAD-TECH/Memmert	7
Laser PSD analyzer	HYDRO2000	1
Infrared Spectrometer	Nicolet	1
TOC Instrument	GE 900	1



Quality Management System---Inspection History

Date	Name/country of the competent Authority	Product	Result
Sep.23-24, 2013	MOH Cyprus	Entecavir	EU GMP, valid until Sep. 24, 2016
Oct.27-31, 2014	US FDA	Entecavir	EIR letter issued on Jun.2015
Nov. 06-07, 2014	CQM	/	ISO14001 and ISO18001 valid until Dec.10, 2017
Oct.17-19, 2015	Zhejiang Food and Drug Administration	Entecavir	GMP written confirmation, valid until Dec. 16, 2018
Jun. 26-28, 2016	Zhejiang Food and Drug Administration	Posaconazole Febuxostat Nebivolol HCl	GMP written confirmation, valid until Jul. 27, 2019
Sep.27-30, 2017	Zhejiang Food and Drug Administration	Apixaban Ticagrelor Lubiprostone	GMP written confirmation, valid until Nov. 05, 2020
May 21-25, 2018	US FDA	Entecavir Febuxostat Lubiprostone Posaconazole Tasimelteon Efinaconazole Nebivolol	Zero 483s



Buildings & Facilities --- API Workshop



Buildings & Facilities --- Clean Rooms



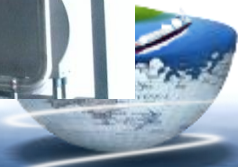
Clean Room



Buildings & Facilities --- *Purified water system*



Ausun Pharma.



Buildings & Facilities --- Warehouse



Buildings & Facilities --- Tank area



Buildings & Facilities --- QC - Lab



QC



EHS Lab

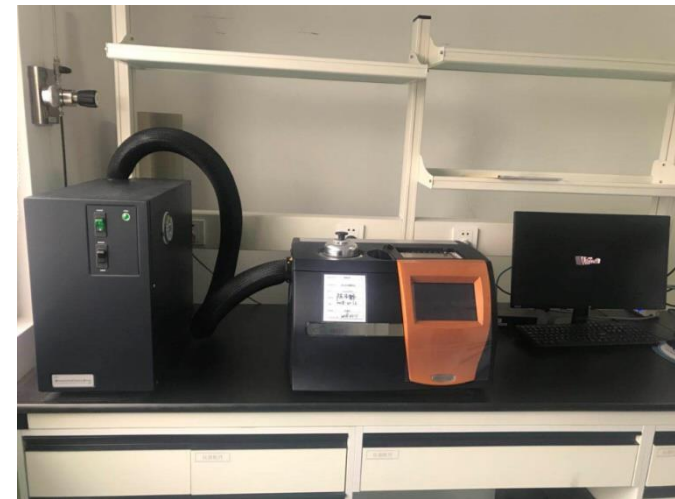
- RC1 : Reaction calorimetric assessment is done for all process steps before scale-up
- DSC / ARC and intermediates
- HAZOP : Risk assessment is done for all products in production



RC1



ARC



DSC



Zhejiang Ausun Pharmaceutical stands for:

- **Expertise and Competence in R+D**
- **Audited by US-FDA, EU-MOH and Japanese PMDA**
- **Customer Focus**
 - **Thriving for a Win-Win Cooperation**
 - **Commitment to earn the Trust of the Customer**
 - **Reliable, Sustainable and Transparent Business Partner**
- **Focus and Priority on Quality and Safety**
- **Protect the IP of the Customer**
- **Focus on the Employees who are an important Asset**
- **Our Main Objective:**
Establish a Long-term Relationship with all Stakeholders





Thank You !

We appreciate your business !