



EXELA

PHARMA SCIENCES



Presentation Overview

- I. Pharmaceutical Industry, Facts, Figures and Uniqueness
- II. Overall Economic Impact
- III. Generic Pharmaceuticals – Essential to Health Care
- IV. Pharma Manufacturing in the US - Strategic Significance
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PHARMACEUTICAL INDUSTRY – FACTS, FIGURES AND UNIQUENESS

Pharmaceutical Industry Overview

Facts, Figures and Uniqueness

Highly regulated - by the FDA

Entry Barrier

- ❖ Upfront intensive investment. (Minimum **\$20-40M**)
- ❖ Facilities and processes need to be established and approved by the FDA before product enters the market – 5 yrs before returns

Operational Inflexibility

- ❖ Inefficiencies in manufacturing (about 50%, *cf* to 70-80% at peers)
- ❖ Opportunities in market place: great flexibility/ huge expenditures

Industry Facts, Figures and Uniqueness

Working Capital

(Pharma Underperforms)

Finished Goods

Average pharmaco holds 180 days of finished goods inventory on hand
Consumer goods industry holds only 60 days' inventory

Raw Materials

Now-a-days, it is about **8-12 months**.

Suppliers shifted the risk and inventory costs on drug manufacturers
Practically all inputs are made to order

Quality Costs (High)

25-30% of conversion costs are for quality standards

Benchmarking

INDIA

- ❖ Prices are 85 to 90% lower than in the US.
E.g.: Tablets cost \$2/1,000. Roughly \$60 for the same in US.
- ❖ Establishing an FDA-inspected plant in India costs about 50% less than in the US.
- ❖ Operation and production costs run 40 to 70% lower.
- ❖ Labor costs are 60 to 70% less than in the US.



OVERALL ECONOMIC IMPACT

Biopharma Industry Overview

Employment

About 854,000 employees in the US in 2014

Employment Multiplier = 5.21.

Supported approximately 3.6 million additional U.S. jobs.

Average annual wages and benefits: More than \$123,000 –
more than twice the U.S. average across all industries

Biopharmaceutical industry jobs are both high-wage and high-quality.

Economic Output

More than \$1.2 trillion
represents 3.8 percent of the total U.S. output in 2014.

(Source: BIO)



GENERIC PHARMACEUTICALS - ESSENTIAL TO HEALTH CARE

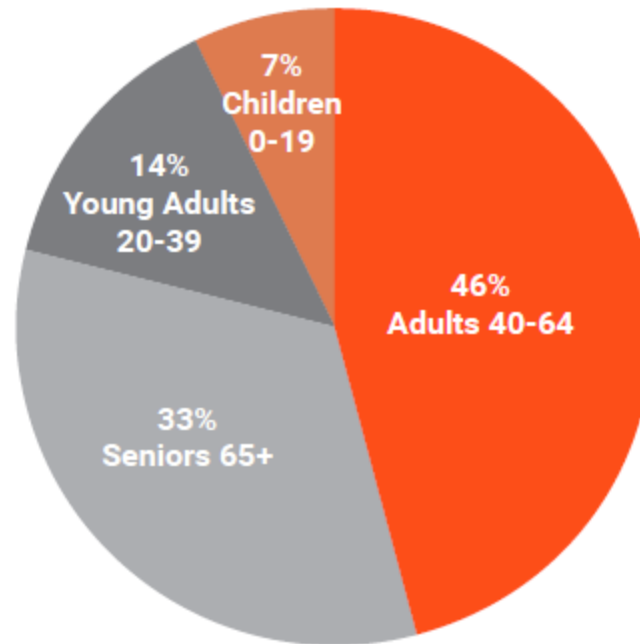
Industry Facts, Figures and Uniqueness

Total U.S. Healthcare Spending



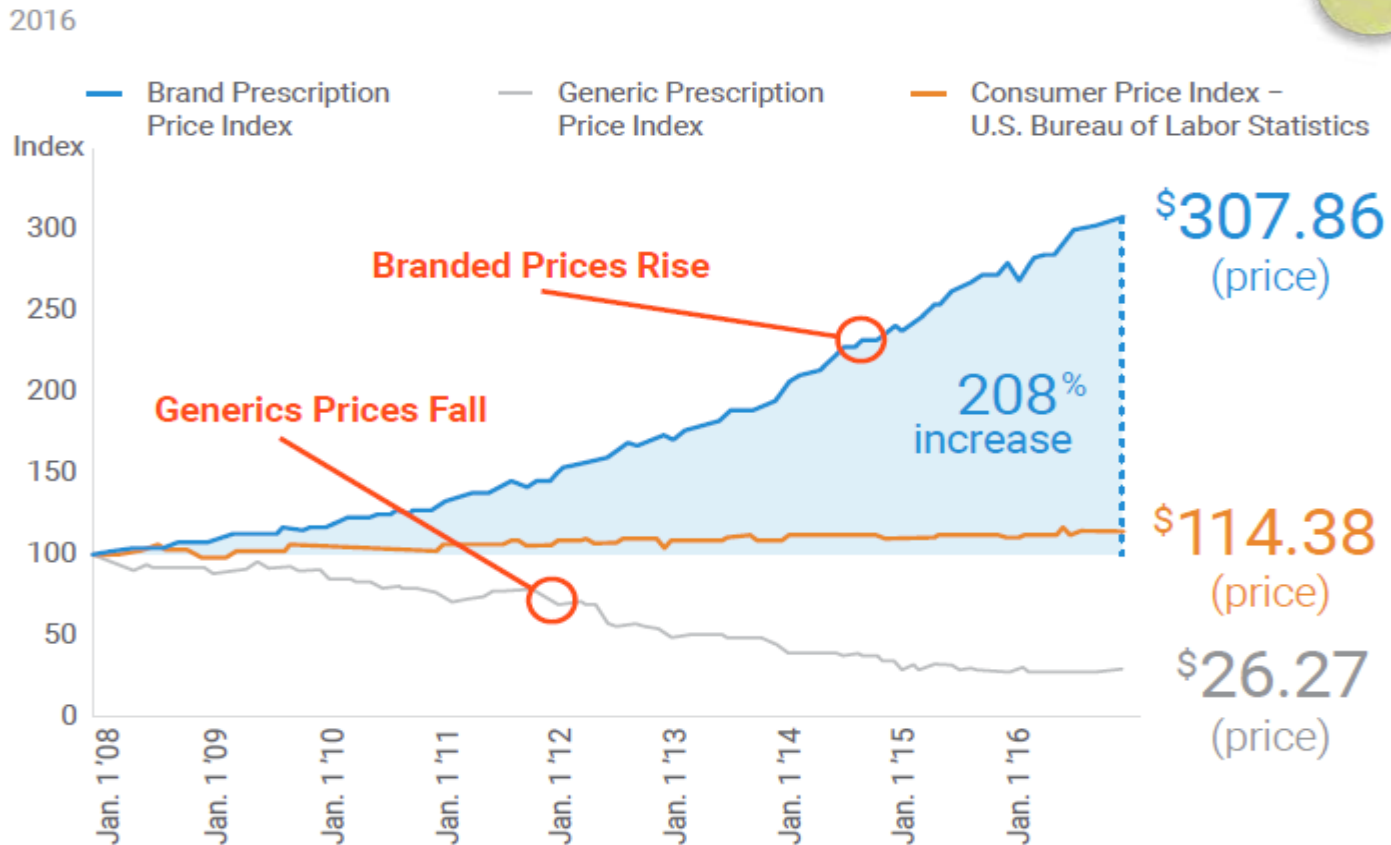
Industry Facts, Figures and Uniqueness

2016 Generic Savings by Patient Age (%)



Industry Facts, Figures and Uniqueness

Express Scripts Prescription Price Index



Industry Facts, Figures and Uniqueness

Nearly 3.9 Billion Generic Prescriptions
were Dispensed in 2016

89%  **26%**

Generics account for 89% of prescriptions dispensed but only 26% of total drug costs in the US.

Brand Drugs Drive Costs

Brands account for only

11%

of prescriptions
(500 million)



yet are

74%

of the cost.
(\$333.9 billion)

Industry Facts, Figures and Uniqueness

2016 Savings **\$253** Billion

10-Year Savings **\$1.67** Trillion

Generic medicines generated \$253 billion in savings in 2016. One-quarter of a trillion dollars.

The U.S. healthcare system has saved \$1.67 trillion in the last decade due to the availability of low-cost generics.



PHARMA MANUFACTURING IN THE US - STRATEGIC SIGNIFICANCE

Manufacturing Generally

- ❖ The vast majority of manufacturing firms in the United States are quite small.
- ❖ In 2015, there were 251,774 firms in the manufacturing sector, with all but 3,813 firms considered to be small (i.e., having fewer than 500 employees).
- ❖ Three-quarters of these firms have fewer than 20 employees.

(Source: U.S. Census Bureau, Statistics of U.S. Businesses)

Manufacturing Exports

Over the past 25 years, U.S.-manufactured goods exports have quadrupled.

- ❖ In 1990 - \$329.5B.
- ❖ In 2014 - \$1.403 trillion.

Trade Surplus/Deficit in 2015

- ❖ \$12.7B surplus with its trade agreement partners
- ❖ \$639.6 billion deficit with other countries.

(Source: U.S. Commerce Department)



EXCESSIVE IMPORTATION

Overdependence on China and India

India and China supply about 60-80% of the US drug products

India and China supply about 70-85% of the US bulk drug (API) requirements

India and China combined have over 1600 API manufacturing facilities

India imports 92% of its raw materials that go into its API and drug product manufacturing from China (about \$6B).

Chinese API/raw materials are four times cheaper than Indian APIs

Recent border tensions between India and China led to the following:

The Commerce Minister said: “the government was fully seized of the issue of the country's dependence on import of APIs and that inbound shipments "are coming from a particular country and as a result, (there are) national security concerns".

Read more at:

[//economictimes.indiatimes.com/articleshow/57790774.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst](https://economictimes.indiatimes.com/articleshow/57790774.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)

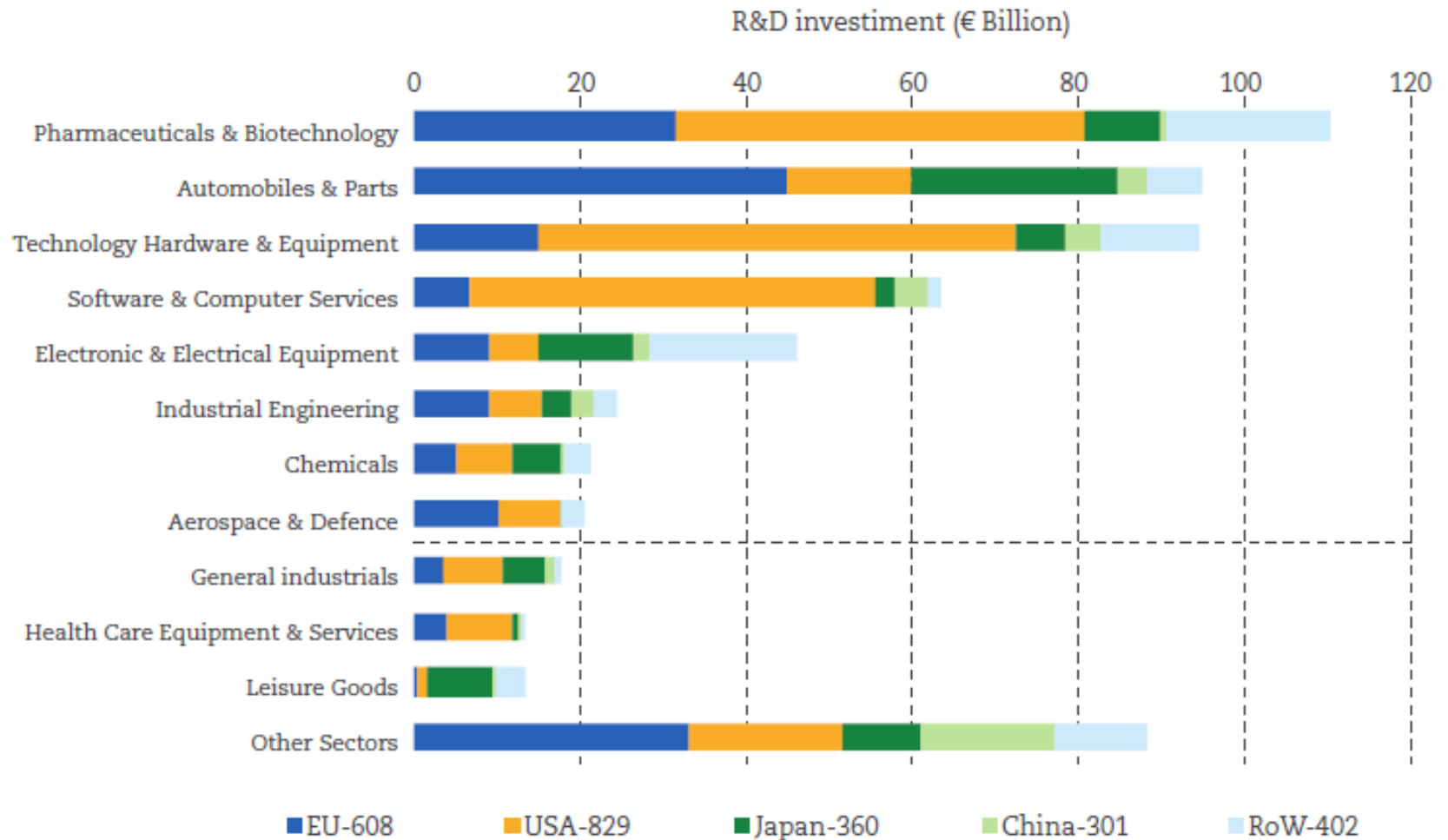
This overdependence is and should be a strategic concern for us in the US as well.

Our current status

- a) Drug shortages are a serious concern; have been happening since 2008. Still no process to get drug products made/released efficiently.
- b) FDA and others cannot turn quickly to address the matters or open to creative solutions
- c) The only quick solution today is importation from another country.

We cannot afford to be depleted of manufacturing capability in the US

R&D Investments



Key Take Away

Our R&D is the highest in the world

**Our manufacturing is disproportional as reflected
by drug product imports**

A Major Strategic Issue



EXELA OVERVIEW

Who is EXELA Pharma Sciences?

“Developer and Manufacturer of sterile products with the healthcare provider and patient in mind”

Key Highlights

- Headquartered in Lenoir, North Carolina
- All development and manufacturing is in the US
- Founded in 2005 - privately held
- Over 275 employees and growing, 30% in Quality functions
- 20,000sf manufacturing space, liquid vials, Lyo vials, IV Bags, ophthalmics
- 80,000sf expansion underway to add 6 new sterile suites and Pre-Filled Syringe capability
- Good cGMP track record with USFDA inspections (2012, 2013, 2014, 2016 & 2017)
- Currently manufacture and market 20 FDA approved sterile injectable drugs, plus 3 injectable drugs in Canada (Health Canada approved)
- Fifteen products filed and pending at FDA, 30+ products in the pipeline
- Focused on differentiated product development, primarily in sterile injectable

EXELA's Economic Impact on Lenoir/Caldwell County

275 high paying manufacturing jobs

Exela Average Salary: \$58,000

Caldwell County Average; \$33,000

Diversification and transformation from furniture to world class state-of-the-art Pharmaceutical Manufacturing.



Full Impact: Employment Multiplier of 5 = 1375
Full Impact: 1375 + 275 = **1,650 Jobs**

What makes EXELA Pharma Sciences different?

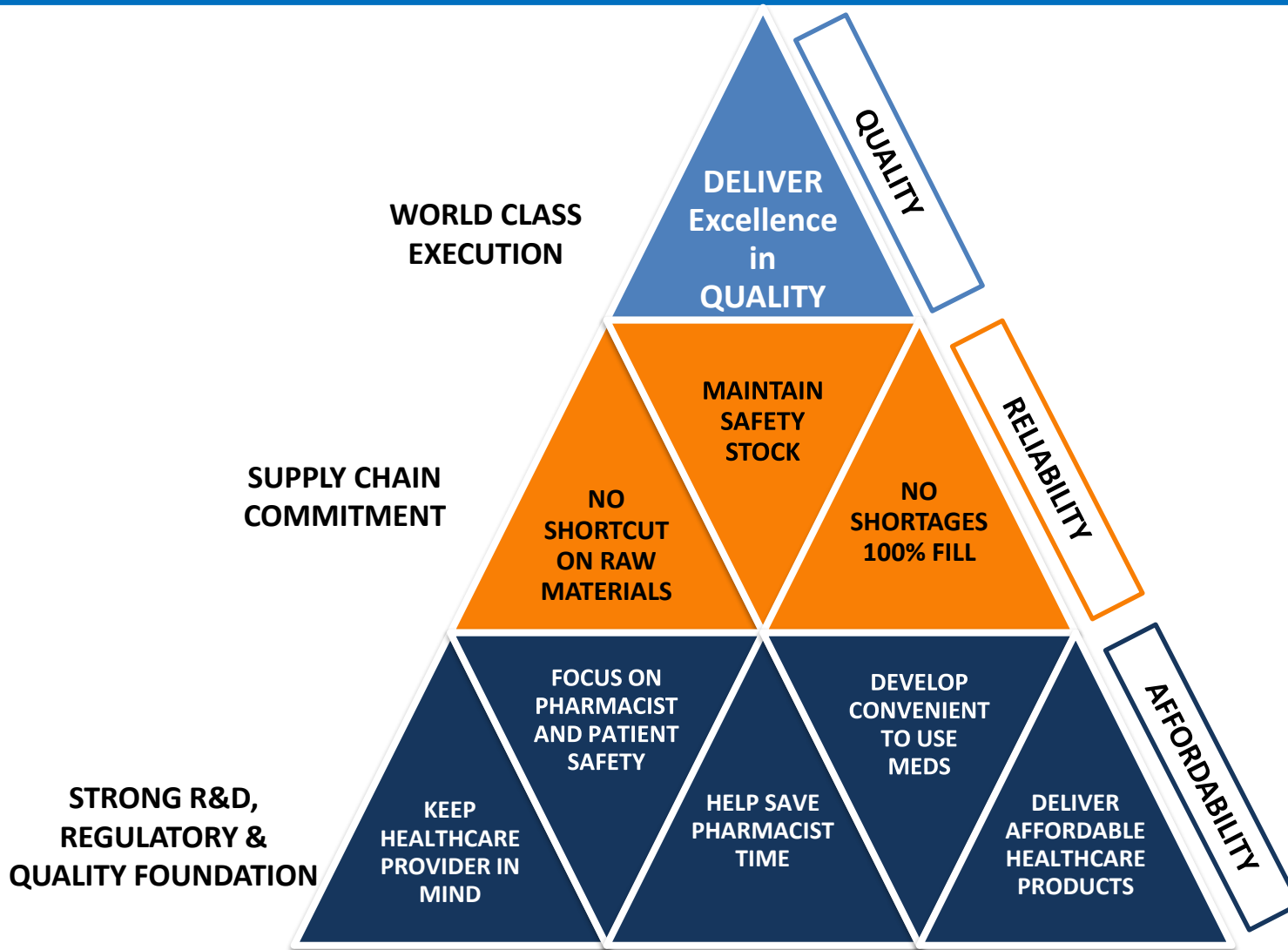
Mission:

“We believe that providing medicines to alleviate human pain and suffering is one of the noblest undertakings. Making medicines affordable and expediting their availability to the needy is a worthy goal. That is EXELA’s focus.”

Our Philosophy

- **Value Add in some way to each Product we manufacture without price gouging**

Unwavering Commitment to End-User



SAFE > PURE > EFFECTIVE

Overview of Facilities, Capabilities and Quality Systems

Facility Overview

20,000 sf manufacturing space (vials and bags)

80,000 sf new manufacturing space under construction (vials, bags, pre-filled syringes)

145,000 sf Corporate, R&D, Quality, Packaging, Warehouse and Distribution Center

165,000 sf future expansion

Manufacturing Capabilities

Current capability - Liquid and Lyo vials (10 mn vials/yr)

Future

IV Bags – High speed bag filler being installed - (5 mn bags/yr)

Pre-Filled Syringes – High speed PFS machine being installed (40 mn/yr)

High Speed Vial Fillers – 2 lines being installed (40 mn vials/yr)

TOTAL by 2019: About 100 mn units/year

Will be in the top 20 sterile small molecule manufacturing facilities in the US

Quality Systems

Very Good cGMP track record - FDA inspections (2012, 2013, 2014, 2016 & 2017)

Commercialized Sterile Products

EXELA Label Products

- Caffeine Citrate Injection - #2 Market Share
- Caffeine Citrate Oral Solution - #1 Market Share
- Potassium Acetate Injection - #2 Market Share
- Verapamil HCl injection - #2 Market Share
- NIPRIDE RTU (sodium nitroprusside) Injection
- GANZYK-RTU (ganciclovir injection) Ready to Use



Partnered Products

- Nicardipine HCL Injection Vials – (WestWard) **(1st APPROVAL; P-IV) (b)(2)**
- Argatroban Injection Vials – (WestWard) **(1st APPROVAL; P-IV) (b)(2)**
- Paricalcitol Injection – (Westward) **(2nd GENERIC; P-IV) (b)(2)**
- Clonidine Hydrochloride Injection – (X-Gen) **(MAJOR SOURCE; Drug Shortage)**
- Magnesium Sulfate Injection – (X-Gen) **(DRUG SHORTAGE PRODUCT)**

Contract Manufactured Products

- Streptomycin Injection – (X-Gen/US and Sterimax/Canada)
- Tranexamic Acid Injection – (X-Gen/US and Sterimax/Canada)
- Hydralazine Injection – (X-Gen/US and Sterimax/Canada)
- LEUTEchniLite Injection – (Lantheus)

NIPRIDE RTU (Sodium Nitroprusside) Ready to Use Vials

Launched March 2017

- The **ONLY** ready-to-use sodium nitroprusside available.
- 0.5mg/mL (50mg /100mL) pre-diluted with normal saline.
- **Previous Product**
- Product was sold for **over 40 years** as a concentrated 2 mL vial that must be diluted in the hospital and protected from light with a shroud, and discarded if not used within 24 hrs
- **Our product** is stable for 24 months – no need to mix in the hospital; no need to use a shroud



GANZYK-RTU – Ganciclovir Injection Bags

Launched September 2017

- The **ONLY** ready-to-use ganciclovir injection available.
- 500mg of ganciclovir in a pre-mixed 250mL bag.
- **Previous Product**
 - Must be diluted in the hospital
 - Has a very pH of about 11.0, which can cause reaction at the site of injection
 - Must take extra precautions to protect personnel from exposure during dilution activities
- **Our Product**
 - Already diluted
 - pH of about 7.5, same as our blood pH
 - no need to protect personnel
 - reduces potential medication errors
 - 24 months shelf life





VIRTUAL FACILITIES TOUR

SAFE > PURE > EFFECTIVE

EXELA
PHARMA SCIENCES

Current Sites – Lenoir, North Carolina



Current Facilities - Laboratory



Formulations Laboratory



Gas Chromatographs and Atomic Absorption Spectrometer



HPLC Wall



Part of QA/QC Laboratory

Current Facilities - Manufacturing



**Vial Filler in Class 1000 suite
with Class 100 RAB**



**Ophthalmic Filler in Class 1000 suite
with Class 100 RAB**



**Class 1000 Corridor to Lyo Suite with
State-of-the art particle monitoring system**



Lyophilizer in Class 100 Suite

Current Facilities – Labeling & Inspection



Kalish Labeler with Vision System & Barcode Reader (70 vials/minute)



Manual Inspection Station

EXELA performs 100% inspection to ensure product quality and integrity

Current Facilities – Labeling & Inspection



IMA Libra High Speed Labeler
(400 vials/minute)



Seidenader High Speed Inspection Machine
(400 vials/minute) (being validated)

**EXELA is building for the future with
high speed automation**

Current Facilities – Water System & Warehouse



WFI High Capacity Water System and Clean Steam Generator



Fully Validated **cGMP** Warehouse



2018 EXPANSION

Exela Expansion - \$25-30M



Preparing to create Clean Rooms



Boiler Room



Water for Injection Equipment



Water for Injection Room



RECOGNITIONS

Exela Recognitions

- 2015

Industry of the Year, Caldwell County

- 2016

Horizons Award by Premier Inc.,
Second Largest Hospital Group Purchasing Organization in the US
for best Supply Chain Performance by a rising Pharma Company

- 2017

Manufacturing Leadership Award - Developing Markets
Awarded by North Carolina Manufacturing Extension Partnership
Presented by Honorable Governor Roy Cooper



DEEP GRATITUDE

Deep Gratitude . . .

- All of Exela's Employees and their Families
- Caldwell County, Economic Development Commission, Lenoir, NC, Deborah Murray
- City of Lenoir, NC
- Blue Ridge Electric Company, Lenoir, NC, Douglas Johnson
- North Carolina Rural Development Center, Raleigh, NC
- North Carolina State Economic Incentives Programs, Raleigh, NC
- US Small Business Administration
- US Department of Agriculture, Bruce Pleasant
- Community Bankshares, Inc., LaGrange, GA, William Stump, Jr.
- Metro City Bank, Atlanta, GA, Nack Paek
- Touchmark National Bank, Alpharetta, GA, Trae Dorough
- Thomas USAF, Atlanta, GA, Mike Thomas and Kathy Morris
- Deerfield Management Company, New York



Thank You



***EXELArate* with us!**

SAFE > PURE > EFFECTIVE

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