



Case study

Quality journey to support life-saving medicine



Manufacturers of



and



# Nice to meet you!

## Introduction:



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# Just the facts

- 270 Employees
- 67 years in business
- 2<sup>nd</sup> Generation Family Business
- Never had an unprofitable year
- Start businesses from scratch – “Green Field”
- 20% to 30% of sales are exported to 54 countries
- ESOP – Employee Stock Ownership Plan – 100%
- Share profits with team members quarterly
- The “Greenest” company in the industry



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# NewAge/AdvantaPure® Company Structure & Background

- AdvantaPure is a product line of NewAge
- **ESOP** (Employee Stock Ownership Plan) 100%
  - **Why is this important to the Customer?**
    - Buying/Selling of Tubing & Hose Companies results in a loss of key industry employees and technical expertise
    - Customers can have assurance that AdvantaPure will be around to give long term customer and technical support
    - All NewAge Team Members are owners

# Purpose Statement

In business to do good, driven to excel

# VISION STATEMENT



NewAge Industries will be independent, employee-owned company 100 years from now. We will be a customer-centric, global innovator, who guides the industry with servant leadership and sustainability.

We will not be sold!



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**BrewSavor**™  
by NewAge Industries

Products



**Our journey towards  
RX 360  
began in 2001,  
which was the start  
of the AdvantaPure®  
product line.**



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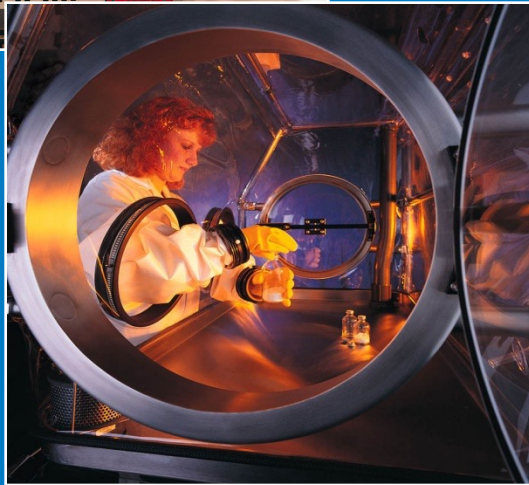
We were begged to supply high purity  
silicone and TPE tubing by Merck



# AdvantaPure® Markets



- Pharmaceutical processing



- Biomedical & Bio-Pharmaceutical

# AdvantaPure Core Competencies

Extrusion

Molding

Assembly

# Stock and custom tubing and hose extrusion



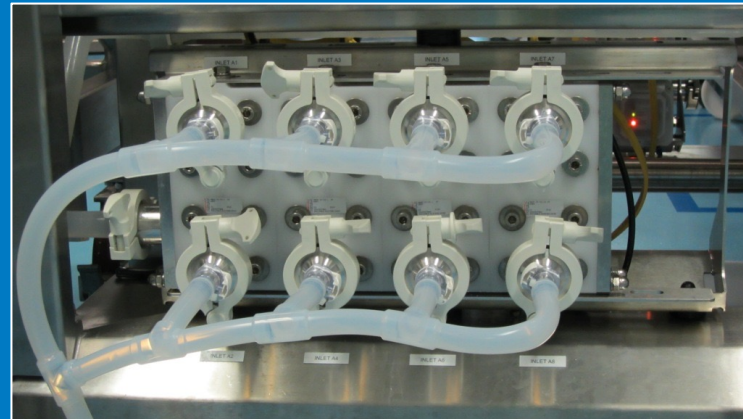
- Manufacturer of AdvantaSil® platinum-cured silicone tubing and braid-reinforced hose

- Manufacturer of AdvantaFlex® TPE tubing



# Current Capabilities & Capacities cont'd

- Manufacturer of BioClosure<sup>®</sup> container closures
- Years of experience with molded tubing assemblies and their components





Failed customer qualification audit of a potential large customer!

Turning point in the company's quality history.

Learning every step of the way.



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**BrewSavor**™ Products  
by NewAge Industries

Quality and Culture  
movement began



Very hard moving from industrial space to  
high-purity.

We needed to change attitudes and  
behaviors.

Some employees did not get it.



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How does making all the employees of the firm owners help the quality movement of the company?

# Tying compensation to quality product & performance

30% ESOP in 2006 and started profit sharing with **all** team members



Profit share plan – pays anywhere 20 %  
to 100 % of salary  
Team members own every mistake – cost  
comes out of their pocket



How does a supplier to the biotech industry help with the quality effort?

Not being sold

# Sustainability



Our view of sustainability is deeper than just green initiatives.

We value succession planning, consistency of supply and technical support.

Our commitment is to not be sold to ensure we will be here 100 years from now!



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# Matured our quality system

- Training and awareness
- Brought in industry and technical experts
- Industry group participation
  - BPE, ISPE, BPOG, BPSA, RX360



- Audit demand increasing
- Quality group and overhead were growing

Willing to push back when recommendations  
or findings don't make sense

Got tired of hearing “the need to justify the trip”

We are an improvement focused organization,  
but frustration was growing



There had to be a better solution



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2018

An International Pharmaceutical  
Supply Chain Consortium

## Started with RX 360

- One of the first companies in single-use to support the program
- The RX 360 SUS audit was more rigorous and applicable than typical company Quality audits
- Asked deeper more relevant questions



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# Single-Use Guide Information:

- Design
- Drawing Management
- Molding
- Tubing
- Film Manufacturing
- Components
- Production Environment
- Assembly
- Membrane (filtration)
- Sterilization
- Inspection



# Single-Use Guide Information:

Standards used to build the audit guide, applicable to each audit:

- ISO 9001 Quality Management Systems
- ISO 14644-2 Cleanrooms and Associated Controlled Environments
- Data Integrity (ALCOA)

Product within the scope of the program:

- Bags/Films
- Filtration (media)
- Tubing
- Molded Components
- Assembled Products

# What value have we seen?

- Over 30 licenses in the last two years
- Savings: 30 audits x 2 days x 2 team members + Reporting follow-ups & CAPA's = \$250,000
  - But most importantly, valuable team member time
- Faster qualification from new customers.
- Relevant audits to the industry we serve
  - Meaningful CAPAs that achieve real improvement

## In summary

RX360 has brought great value to our organization and helped advance our quality systems while simultaneously increasing our company presence.



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# Thank you for your time!

## Questions?



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