





GLASS

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"Hidden in the glass formulation of crystal sand, limestone, and soda ash is a chemistry, which to this day is not fully understood. It takes place when these ingredients are transformed by intense heat into a syrupy, viscous mass, which dissolves quartz crystals and changes into a noncrystalline form upon cooling"

- John A. Rossi, A Brief History of Glassmaking, 1998







NATURAL GLASS



VOLCANIC OBSIDIAN



METEOR TEKTITE



FULGARITE

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EARLY GLASS MAKING

The ancient Egyptians may have been the first people to learn how to make glass as far back as 3500 BC. They learnt how to heat sand in a very hot furnace and then blow the molten sand into glass. They made glass jars and glass beads. This picture show's an ancient Egyptian wall painting of workmen blowing glass in a furnace.





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EARLY GLASS MAKING

Glass blowing as we know it today, seems to have begun in the first century B.C. in then-Roman Syria. These glass craftsmen used a metal tube to blow air pockets into hot glass. Taking the potential of glass one step further, they then blew glass into molds, creating a wide variety of shapes for vessels and containers. This innovation would continue to distinguish the Italians as glass masters of the craft for centuries to come.





ROMAN GLASS VIALS

By the 1st century AD, the technique of glassblowing revolutionized the art of glass-making and allowed for the production of small medicine, incense, and perfume containers in new forms. Glass unguentaria, bottles & vessels of various shapes were manufactured with blowpipes, free-blown, or mould-blown, and were prevalent throughout the ancient Roman Empire, from Egypt to Cologne.

EUROPEAN GLASS

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Romans spread glassmaking through Europe. Venetian and German skilled craftsmen advance glass making techniques. Establishing renowned centers of excellence.

Glass artisan in Murano, Venice Italy.

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AMERICAN GLASS MAKING

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The first attempt at glassmaking in the New World was in Jamestown, Virginia, in 1608. Other ventures were tried in New York, Philadelphia and Salem, Massachusetts.





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AMERICAN GLASS MAKING

It wasn't until 1739 that the first successful glass factory was established by Caspar Wistar in Alloway, New Jersey. The Wistar factory operated until about 1882. Wistar defied English policy forbidding all manufacturing in the Colonies. Wistar was a contemporary of America's founding fathers and a friend of Benjamin Franklin. Supplying glass articles for Franklin's experiments.



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CIRCA 1890 EARLY PHARMACEUTICAL GLASSMAKING

Flint Tank No. 12, Making Drug Ware. Whitall Tatum Co., Millville, NJ.

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"MILLVILLE"

"Down in southern New Jersey, they make glass. By day and by night, the fires burn on in Millville and bid the sand let in the light. Millville by night would have delighted Whistler, who loved gloom and mist and wild shadows. Great rafts of wood and big, brick hulks, dotted with a myriad of lights, glowing and twinkling every shade of red. Big, black flumes shooting out smoke and sparks; bottles, bottles, bottles, of every tint and hue, from a brilliant crimson to the dull green that marks the death of sand and the birth of glass."

- CARL SANDURG (1904)

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AUTOMATION IN GLASS BOTTLE MAKING

In 1904, Michael Owens is granted a patent for a "glass shaping machine".

A machine, in one shift could produce more bottles, than a five man crew could in a week. Enough bottles could cost effectively be produced for mass packaging.



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19TH & EARLY 20TH CENTURY

PHARMACEUTICAL GLASS



PARK DAVIS

Early 20th Century

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FRENCH AMBER JARS

19th Century



WOOSTER & ADAMS

19th Century

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TUBULAR GLASS VIALS

In 1912, E. Danner (Libbey Glass Company) developed the first continuous tube drawing process in the USA, which works in horizontal direction. In 1918 he received a patent. In 1929 a vertical drawing process was developed by L. Sanches-Vello in France.



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20TH CENTURY

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PHARMACEUTICAL GLASS



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STILL WIDELY USED, STILL NOT FULLY UNDERSTOOD

PHARMACEUTICAL GLASS TODAY

KENNETH CHANG

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"Scientists still disagree, with some vehemence, about the nature of glass."

"The Nature of Glass Remains Anything but Clear" NY Times, 2008

PETER HARROWELL

"They're the thickest and gooiest of liquids and the most disordered and structureless of rigid solids..."

A professor of chemistry at the University of Sydney, Australia

PHILIP W. ANDERSON

"The deepest and most interesting unsolved problem in solid state theory is probably the theory of the nature of glass and the glass transition."

Nobel Prize-winner, 1995



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BILLIONS & BILLIONS





PHARMACEUTICAL GLASS TODAY





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RECALLS REPORTED

FDA Warning Letters Issued Associated w/ Glass Issues for Sterile Drug Products. 2011 PDA/FDA Glass Quality Conference, Arlington, VA May 23-24, 2011.



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TYPES OF GLASS ISSUES REPORTED

In Sterile Drug Product Recalls. 2011 PDA/FDA Glass Quality Conference, Arlington, VA May 23-24, 2011.



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FDA ADVISORY TO DRUG MANUFACTURERS:

FORMATION OF GLASS LAMELLAE IN CERTAIN INJECTABLE DRUGS

[3-25-2011] The U.S. Food and Drug Administration is advising drug manufacturers of the potential formation of glass lamellae (glass fragments) in injectable drugs filled in small-volume glass vials[1]. Several drugs have recently been recalled due to this problem.[2] Glass has many advantages over other packaging materials, but one well-known disadvantage is the potential for glass under certain conditions to shed thin, flexible fragments called "glass lamellae." [3],[4] These lamellae are shed from the interior surface of the glass container directly into the drug and are difficult to detect by visual inspection. To date, no adverse events have been reported nor can any be directly attributed to this phenomenon. However, there is the potential for drugs administered intravenously that contain these fragments to cause embolic, thrombotic and other vascular events (e.g., phlebitis); and, when administered subcutaneously, to lead to development of foreign body granuloma, local injection site reactions, and increased immunogenicity.[5] The following conditions have been associated



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CAPLINE HEADER ELEMENT

INDUSTRY RESPONSE







RECALLS DUE TO METAL PARTICLES EMBEDDED IN GLASS VIALS

David J. Jaworski Senior Policy Advisor CDER, Office of Compliance, Office of Manufacturing Quality

2018 PDA Glass Quality Conference January 23, 2018



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RECALLS DUE TO GLASS PARTICLES IN VIALS

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PDA GLASS QUALITY SURVEY 2017

How would you rate the overall glass container quality supplied by your suppliers?

Answer Options	2013		2017	
	Response Percent	Response Count	Response Percent	Response Count
Unacceptable	0.0%	0	0.0%	0
Poor	4.1%	2	0.0%	0
Fair	51.0%	25	21.4%	6
Good	40.8%	20	78.6%	22
Exceptional	4.1%	2	0.0%	0
	Answered	49		28
	Skipped	32		16





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PDA GLASS QUALITY SURVEY 2017

In your opinion, has glass quality increased or decreased over the past five (5) years?

Answer Options	2013		2017	
	Response Percent	Response Count	Response Percent	Response Count
Increased	52.0%	26	60.7%	17
Decreased	16.0%	8	7.1%	2
Not Changed	32.0%	16	32.2%	9
	Answered	50		28
	Skipped	31		16





LOOKING FORWARD

- Tens of Billions of Pharmaceutical Glass Containers are Produced Annually Worldwide
- Significant Growth in Injectable Drugs Expected to Continue for the Next 10 Years
 - Over a Third of NDA Approvals Were Parenterals in 2017
 - Trend Expected to Increase
- Over Eighty Per Cent Packaged in Glass
- Initially Over Eighty Per Cent of New Drug Approvals are in Vials
- Unique Challenges of Complex Biopharmaceutical Products Requires Technological Advancements in Glass Packaging
- Glass Will Remain Significant in the Future of Parenteral Packaging, But...

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NOT YOUR GRANDFATHER'S GLASS







THANK YOU

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