

valisure  
the pharmacy that checks

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# VALISURE IS THE FIRST ANALYTICAL PHARMACY

Valisure is an online pharmacy attached to an analytical laboratory. We're the only pharmacy that chemically tests every batch of every medication we sell at no additional cost to consumers.

<b>Valsartan</b> Lot: VUSD18007-A	
<b>VALISURE ANALYSIS</b>	
<b>Dosage: 320 mg</b>	(± 5%)
Active Ingredient: Valsartan	
Spectral Match: Yes	
<b>Major Inactive Ingredients</b>	
Microcrystalline Cellulose	
Crospovidone	
Lactose Monohydrate	
<b>Impurities</b>	
NDMA	Pass
NDEA	Pass
DMF	Pass
<b>Dissolution</b>	
Disintegration Test	Pass
Drug Release Time	< 3 hours
<b>Approved</b> Kaury Kucera, PhD <i>Kaury Kucera</i>	



**QUALITY ASSURANCE IN MEDICATIONS.**  
*We're the pharmacy that checks.*

# QUALITY ISSUES IN THE U.S. ARE VERY REAL

## 2015 FDA WHITE PAPER:

“Product recall and defect reporting data demonstrate **unacceptably high occurrences of problems** attributed to inherent defects in product and process design; these data further indicate failures in the implementation of manufacturing process scale-up as well as routine production.”

“**FDA has no formal means for quality surveillance**, except through inspections,” and “inspection findings have not been a reliable predictor of the state of quality.”

## IN THE UNITED STATES:



~80% of drug ingredients from India or China



~3 drug recalls per day



~100 recalls per year with risk of death



~90% of prescriptions are generic


**Many issues are never caught. Quality is only checked occasionally at the manufacturer and is self reported.**

Lot-to-lot variability in anti-epileptic medication causes 2.3x increased incidence of seizures

– *Harvard Medical School Study (n=1762)*

# SOLUTION: AN ANALYTICAL PHARMACY



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Kaury Kucera, PhD	

## CHEMICALLY VALIDATED MEDS

Every batch screened

Certificate of analysis  
with every bottle

Shipped direct to patient

No additional cost

# A NEW CLASS OF MEDICATION

Traditionally there have been only two primary options for most medications: brand or generic. **NOW THERE IS A THIRD OPTION.**

	 BRAND	 GENERIC	 VALIDATED GENERIC
QUALITY ASSURANCE	✓	X	✓
COST	X	✓	✓
CERTIFICATE OF ANALYSIS	X	X	✓

Valisure's unique chemically validated generics come with added quality assurance and a batch-specific certificate of analysis, and with the same low cost of generics.

# HOW AN ANALYTICAL PHARMACY WORKS

PHARMA  
INDUSTRY

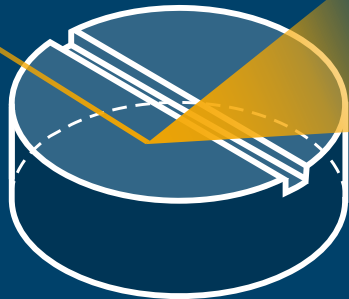


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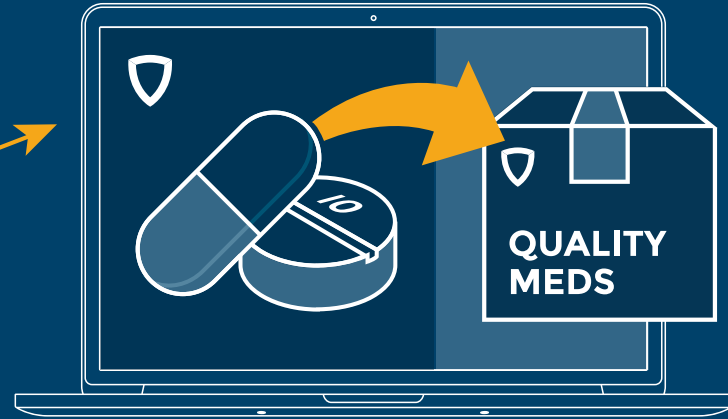
BAD BATCHES

QUALITY BATCHES



VALISURE  
LAB TESTING

VALISURE  
PHARMACY



1. **Buy meds** from US distributors
2. **Analyze sample** using proprietary systems  
• *Failures reported*
3. **Order** large quantity of passing batch
4. **Ship** quality meds with batch-specific certificate

**8/7/18 FDA INSPECTION:**

"No other such entity exists  
in the United States."

# OUR STORY

Founders Adam Clark-Joseph and David Light reconnected after Adam suffered serious complications caused by batch variability of his anticonvulsant medication. Upon further research, they began to grasp the magnitude and pervasiveness of the problem throughout the pharmaceutical industry. Adam and David brought together a team of like-minded scientists and pharmacy experts to develop and deploy a solution. The result was Valisure, a company dedicated to preventing anyone from suffering adverse effects from low quality medications.



**DAVID LIGHT**  
*Founder & CEO*

David is a biotech entrepreneur and scientist. A graduate of Yale University, David studied molecular biology and has worked in a variety of scientific and business roles at start-ups like Synthetic Genomics, 454 Life Sciences and Ion Torrent. At Ion Torrent, David developed and deployed key technologies that led to its \$725M acquisition and ran its flagship technology programs through development and global commercialization.



**ADAM CLARK-JOSEPH, PHD**  
*Founder*

Adam is an assistant professor of finance at the University of Illinois at Urbana-Champaign. He holds a PhD in economics from Harvard, a master's degree from Cambridge, and bachelor's degrees in math and economics from Yale. Adam was the recipient of a NSF Graduate Research Fellowship and a Gates Cambridge Scholarship. His academic research focuses on algorithmic trading, and empirical applications of high-performance computing and novel statistical methods.



**KAURY KUCERA, PHD**  
*Chief Scientific Officer*

Dr. Kaury Kucera is Valisure's Chief Scientific Officer, where she oversees all lab activities including medication testing and test design. She is a pharmaceutical biochemist with degrees in molecular biophysics and biochemistry from the University of Chicago and Yale University. Her studies included natural product medicinal chemistry in the Department of Molecular Biophysics and Biochemistry at Yale University and structure-based drug development and screening in the Department of Pharmacology at Yale University. Prior to joining Valisure, Dr. Kucera led a large-scale and multi-year effort by Yale University aimed at discovering new organic compounds from the Amazon rain forest; in that context, Dr. Kucera oversaw the development of hundreds of unique assays.



**DEANNA AKINBAJO, PharmD, MPH**  
*Chief Pharmacist*

Dr. Deanna Akinbajo received her Pharmacy doctorate (PharmD) from Albany College of Pharmacy and Health Sciences. She completed a Pharmacy residency (PGY-1) at Waterbury Hospital where she conducted research, and precepted and mentored students, while holding a position as an adjunct professor at the University of Connecticut. Dr. Akinbajo received her Bachelor's degree in Communications with a certificate in Conceptual Foundations of Medicine from the University of Pittsburgh and her Master's in Public Health (MPH) from the University at Albany. As Valisure's Chief Pharmacist, Dr. Akinbajo brings her numerous years of experience working in retail pharmacies, long term care facilities, and a hospital as a Clinical Pharmacist.

# PRESS THE WASHINGTON POST

By Carolyn Y. Johnson – November 2019

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## The Washington Post

*Democracy Dies in Darkness*

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“NEW HAVEN, Conn. — The escalating global recall of Zantac, the heartburn pill that once ranked as the world’s best-selling drug, has its roots not in government oversight or a high-profile lawsuit but in a tiny online pharmacy here whose founders feared that U.S. drugs might not be as safe as people think.”

“The pharmacy, Valisure, is a start-up with only 14 full-time employees. But since its scientists alerted American regulators that Zantac and its generic form, ranitidine, contained a chemical thought to cause cancer, more than 40 countries from Australia to Vietnam have either stopped sales, launched investigations or otherwise stepped in to protect consumers from possible health risks.”

“Valisure sees that gap as an opportunity. The company first alerted U.S. regulators in June that Zantac and ranitidine products contained a probable carcinogen. In September, Valisure filed a citizens petition to have the products pulled from the market entirely, and the FDA issued an alert to the public that the agency had learned some products contained NDMA. Follow-up testing had led Valisure’s scientists to suspect that the drug wasn’t contaminated but that the drug itself is unstable and could form NDMA, particularly in the conditions found in the stomach.”



*A sample with NDMA, an impurity that has been linked to an increased risk for colorectal and uterine cancers, that was found to be formed by ranitidine, a drug used to treat and prevent heartburn by reducing stomach acid.  
(Stan Godlewski for The Washington Post)*

**“We always thought of consumer protection . . . as an important part of what we would do, but I never appreciated how big of a problem we’re watching over,” Light said. “We find more problems than we have resources to fully investigate.”**

“For Valisure’s scientists, finding NDMA in ranitidine was a particularly dramatic example of the kind of discovery they make routinely. Valisure checks the chemical makeup of drugs before it ships them to consumers, and it rejects more than 10 percent of the batches because its tests detect contaminants, medicine that didn’t dissolve properly or pills that contain the wrong dose, among other issues. Since late 2018, Valisure has reported more than 50 problems directly to drug companies. Occasionally — as in the case of Zantac — their scientists find a problem so urgent they play the role of watchdog.”

**“I had a fairly dim view of drug quality in the United States going into this, but we’ve discovered tons of problems I never even thought of — and they’re all over the place,” said Adam Clark-Joseph, one of Valisure’s founders.**



# PRESS HIGHLIGHT BLOOMBERG BUSINESSWEEK COVER - [Article](#)

By Anna Edney, Susan Berfield, and Evelyn Yu – September 2019

“To gauge what testing might turn up, consider Valisure LLC, an online pharmacy in New Haven, Conn., that opened in 2018 and tests every drug it orders. It’s rejected more than 10% of the medication batches it’s purchased, according to CEO David Light. Grounds for rejection could be a drug not having the proper amount of active ingredient, or not dissolving as it’s supposed to, or containing impurities.”

**“Valsartan is just the one we caught. Who knows how many more are out there?”**



“Light says he’s spoken with people in the industry about his findings. “The overwhelming response is, ‘We know there’s a problem, but it’s not our problem,’” he says. “There’s no liability at any one point. The whole system is so complicated you could point at anybody.”

**“The only element who cares in this whole global supply chain is patients.”**

# PEOPLE ARE TALKING ABOUT US

**A tiny pharmacy is identifying big problems with common drugs, including Zantac** - *Washington Post* - [Article](#)

**Carcinogens have infiltrated the generic drug supply in the U.S.** - *Bloomberg Businessweek* - [Article](#)

**DeLauro Calls on FDA, HHS to Recall Drug Commonly Found in Zantac** - *Congressional Press Release* - [Article](#)

**Potentially dangerous chemical found in popular heartburn pill Zantac** - *CBS Evening News* - [Article](#)

**How Do You Stop Taking Recalled Medications If You Don't Know They've Been Recalled** - *Bloomberg Businessweek* - [Article](#)

**Zantac has low levels of a cancer-causing chemical, the F.D.A. says** - *The New York Times* - [Article](#)

**FDA finds probable carcinogen in some versions of Zantac** - *Wall Street Journal* - [Article](#)

**Heartburn Drugs and Cancer: What Are the Risks?** - *WebMD* - [Article](#)

**Three ways to fix the drug industry's rampant dysfunction** - *Wired* - [Article](#)

**Zantac is prescribed 15 million times a year. So how did it become a potential cancer risk?** - *USA Today* - [Article](#)

**'Rapid release' Tylenol gelcaps are slower to dissolve than cheaper tablets, study finds** - *Washington Post* - [Article](#)

**Pharmacy tests turn up another cancer-causing compound in heart drugs** - *CNN* - [Article](#)

**The Zantac-Ranitidine weirdness just got stranger** - *The People's Pharmacy* - [Article](#)

**What we know about the possible carcinogen found in Zantac** - *Scientific American* - [Article](#)

**Pharmacies pull Zantac over concern that contaminant poses cancer risk** - *NPR* - [Article](#)

**At What Cost: The Real Cost of Cheaper Drugs** - *Bloomberg* - [Article](#)

**Online pharmacy flags possible new impurity in blood pressure drug** - *Physician's Weekly* - [Article](#)

**Explained: Why India, US haven't recalled acidity drug Ranitidine but France & Canada have** - *The Print (India)* - [Article](#)

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