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# PRODUCT

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Zhongxin Zhou, Gilead Alberta  
Find out more at: [www.gilead.com/yir2016](http://www.gilead.com/yir2016)



GILEAD

## PRODUCT

With 23 marketed products and hundreds of ongoing and planned clinical studies, we are focused on solving some of the biggest health challenges of today. Last year, Gilead produced and distributed 33 million bottles of oral medicines and approximately 11 million vials of liquid medicine worldwide.



Ron Taber, Gilead  
San Dimas

Gilead's antiretroviral therapies have helped transform HIV infection from a fatal and debilitating disease into a chronic, manageable condition. We now have nine medicines available to patients and providers to help address the diverse needs of HIV patients worldwide. Through the advancement of PrEP, Gilead is also helping reduce the chances of acquiring HIV infection in HIV-negative individuals at high risk. However, we are not stopping there. We are also working to end the epidemic by conducting early-stage clinical research to identify novel agents and strategies that could play a role in eradicating HIV infection in the body.

Gilead is also transforming treatment of HCV. In three years we have launched three HCV therapies, including the first pan-genotypic treatment for the disease, Epclusa® (sofosbuvir/velpatasvir), which was approved in 2016. Today more than one million patients worldwide have been treated with a sofosbuvir-based regimen. We continue to work to address unmet needs with an additional fixed dose combination currently under evaluation as a potential salvage therapy for the treatment of patients who failed other direct-acting antiviral therapies.

To treat HBV, Gilead offers medicines that help patients manage chronic infection. Our research team continues to work on ways to achieve a finite duration of treatment such that patients can control or eliminate the virus without having to endure a lifetime of therapy.

As Gilead works to transform and simplify care by delivering innovative and effective treatments, we are also seeking to reduce the environmental and social impacts associated with manufacturing, packaging and distribution of our products. From implementing environmental process improvements at our manufacturing sites to developing a company-wide Supplier Inclusion program to create opportunities for underrepresented suppliers, Gilead is actively minimizing environmental and social impacts in its supply chain.

### SUPPLY CHAIN AND PROCUREMENT

Through close oversight and strategic decision-making, we not only maintain compliance, but also improve social and environmental performance in our supply chain. Gilead's procurement and supply chain initiatives include responsible sourcing, auditing procedures, manufacturing and distribution and green chemistry.

## RESPONSIBLE SOURCING

In 2016, Gilead's procurement organization commenced development of a new Supplier Code of Conduct to integrate social and environmental indicators into its supply chain and procurement process. These indicators include supplier diversity, labor practices, human rights, environmental health and safety, environmental impact and mentoring and investment programs to help advance supplier programs and policies.

## SUPPLIER INCLUSION

Gilead's procurement initiatives included small businesses and/or businesses owned by women, minorities, LGBT individuals, veterans and service-disabled veterans.

Gilead's Supplier Inclusion program is designed to empower all business units to leverage the proven benefits of an inclusive team, including suppliers, to increase diversity of thought.

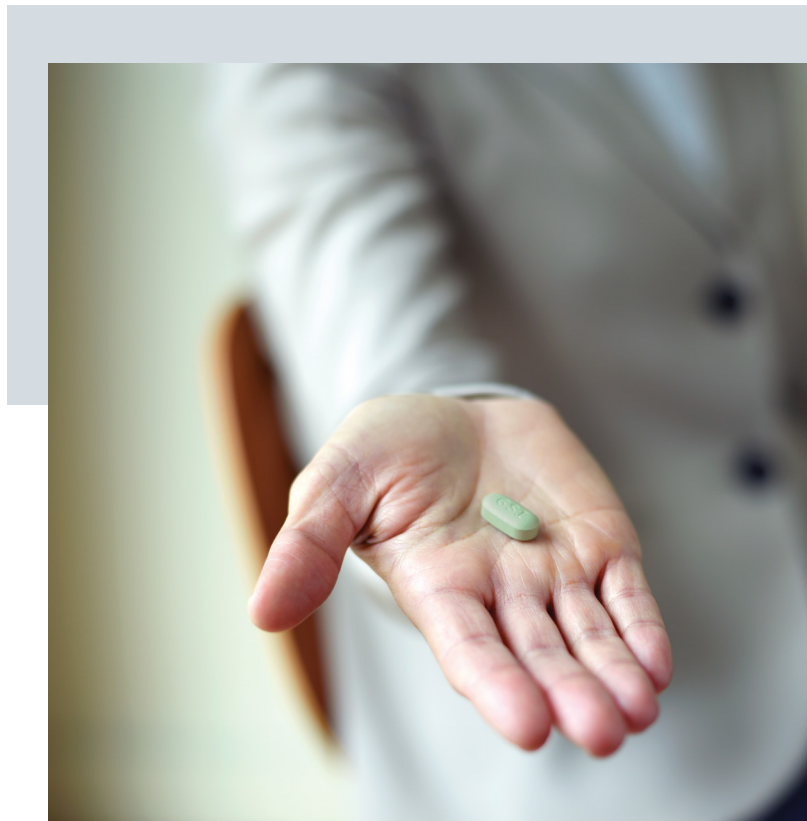
### ***The goals of this program are to:***

- Increase innovation and agility in the supply chain
- Positively impact local communities
- Meet and/or exceed federal regulations

Suppliers are identified and selected not only based on their ability to contribute value to Gilead's business, but also to help create economic opportunity for underrepresented suppliers.

### ***Influential supply chain partnerships in 2016 included:***

- Diversity Alliance for Science (DA4S) — identifies small and/or diverse businesses with whom Gilead and its industry peers can partner.
- Institute for Supply Management (ISM) Supplier Diversity Pharmaceutical Forum — a forum where members are dedicated to:
  - Driving business results through innovation, agility and performance
  - Mentoring and developing small and diverse suppliers
  - Inclusive procurement
  - Sharing best practices
- Western Regional Minority Supplier Development Council (WRMSDC) — supports the growth and welfare of minority communities by championing the use of minority-owned businesses in Northern California, Nevada and Hawaii.



Gilead takes measures to ensure that its suppliers adhere to ethical standards. In some cases, site audits are conducted to evaluate compliance with regulatory policies, including the Foreign Corrupt Practices Act (FCPA), the U.S. Trafficking Victims Protection Act (TVPA) and other applicable labor, anti-corruption and environmental regulatory policies.

## AUDITING PROCEDURES

Gilead's suppliers are regularly monitored as part of the company's supply chain audit program. During these audits, the partnership is evaluated for potential discrepancies with regulations or the company's own guidelines. If any violations are identified, corrective action is recommended and noted for follow-up evaluations. Certain violations, such as the use of forced labor, human trafficking, or environmental negligence would result in a terminated agreement and the supplying organization would be removed from Gilead's supply chain.

During audits performed in 2016,  
no material violations of our Code of  
Ethics were identified.



## MANUFACTURING AND DISTRIBUTION

We contract with third parties to manufacture the majority of our active pharmaceutical ingredients (APIs) and drug products and our external supply chain continues to expand around the world. Our internal manufacturing facilities are located in Foster City, San Dimas and Oceanside, California; Edmonton, Alberta, Canada and Cork, Ireland.

Gilead's suppliers for APIs and products must observe Good Manufacturing Practice (GMP) regulations as designed by the United States Food and Drug Administration (FDA) and other relevant health authorities worldwide. GMP covers all aspects of production: manufacturing procedures of dosage products and APIs from the starting materials, premises and equipment to the training and personal hygiene of staff.



Reusable thermal blanket wraps are used to minimize temperature excursions for pallet shipments for APIs.



Finished goods distribution is handled either via temperature-controlled containers or trucks; these are fully compliant with drug transportation safety guidelines, eliminating the need for additional temperature-controlled packaging.



Medicines transported by air utilize reusable containers that adhere to strict temperature and purity standards.



## GREEN CHEMISTRY

As part of the lifecycle management of all products, there may be opportunities to refine the process to achieve chemically equivalent results while reducing or substituting out undesirable inputs such as organic solvents. Limiting organic solvents helps lower Gilead's environmental impact since these solvents are typically derived from nonrenewable sources and may have hazardous or toxic properties. We have undertaken efforts to reduce the use of organic solvents and other harmful substances from our manufacturing process.

Gilead's Process Research and Development team, including the Commercial API Process Optimization (CAPO) group, based in Foster City, California, and Edmonton, Alberta, Canada, is responsible for integrating green chemistry principles into the design and development of chemical processes for commercial APIs.

In 2016, Gilead evaluated new opportunities to use enzymatic reactions and flow chemistry to reduce chemical processing steps and improve product yields, while minimizing the environmental impacts associated with manufacturing products.

Gilead's CAPO group also made significant progress developing API process improvements for the manufacturing of APIs for HIV and HCV therapies in 2016.

Implemented at Gilead's development manufacturing facilities, these process improvements reduced solvents, halogenated solvents, aqueous washes and organic waste, while increasing yields.

After verifying the feasibility of these optimizations at full scale, Gilead began testing the latest API process in commercial reactors at the end of 2016. Following rigorous tests, the optimizations successfully demonstrated viability and CAPO is now in the process of generating the data required for regulatory approval in countries where Gilead manufactures and distributes HIV and HCV medicines.

### *In 2016, Key API Process Improvements Included:*

<i>Therapy API</i>	<i>HIV TAF</i>	<i>HCV SOF</i>
Reduction in Solvents	12%	35%
Reduction in Halogenated Solvents	22%	41%
Reduction in No. of Aqueous Waste	20%	9%
Reduction in Organic Waste	9%	17%
TAF: Tenofovir Alafenamide SOF: Sofosbuvir		

### **SAFETY, LABELING AND COMPLIANCE**

Product safety is paramount at Gilead. Every product goes through rigorous development, testing and clinical trials phases. All Gilead products are labeled and marketed pursuant to governing policies and regulations. There were no marketing or labeling violations in 2016 resulting in a fine or warning.

*Astrid Clarke and  
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Gilead Seattle*

