

GS1 HEALTHCARE

CELEBRATING 15 YEARS

Looking back at all we have achieved together



As GS1 Healthcare celebrates its 15th anniversary this year, we are reminded of just how much we have accomplished together and the outstanding impact we have made to help improve accuracy, visibility, and traceability across healthcare to improve patient safety worldwide. In honour of this momentous milestone, we are taking a moment to reflect on the last 15 years and as well as imagine what the future holds.

Our Beginning

2005-2010



Establishing the Global Healthcare User Group in 2005 has allowed us as healthcare providers to interact with solution providers, medical device and pharma suppliers, as well as our peers and other key stakeholders worldwide in a neutral and trusting environment. This engagement has undoubtedly led to innovative standard based solutions that have helped improve patient safety and increased efficiency whilst driving down the cost of healthcare delivery. No one could have imagined in 2005 what a great success story it would truly become.



Feargal McGroarty | National Haemophilia System Project Manager |
IMS Department | Hospital 1 MF | St James's Hospital | GS1 Healthcare
Tri-Chair

On the 23rd of May 2005, twenty-three visionary healthcare stakeholders from around the world came together in Princeton, New Jersey to discuss enhancing patient safety. The meeting, which comprised experts from the pharmaceutical and medical devices industries, convened for two busy days after which the group was convinced that global standards would contribute to improving patient safety and to increasing supply chain efficiency. The GS1 Healthcare User Group (the 'HUG', which was later renamed to GS1 Healthcare), was thus established, a mission & vision defined and the first work teams created. The aim of the global user group was to lead the Healthcare sector in the development and implementation of global standards.

Over the next five years the group continued to increase its engagement with regulatory bodies and stakeholders worldwide, to improve patient safety and supply chain efficiencies. From the development and introduction of the GTIN Allocation Rules for Healthcare, to the work on serialisation, data carriers, and traceability, GS1 Healthcare was able to provide regulatory bodies with rationale for why they should adopt the GS1 global standards already being implemented by industry. Local GS1 Healthcare user groups, facilitated by GS1 Member organisations, soon started to form and were driving activities across numerous countries.

Continued Growth

2011-2015



“As the importance of traceability and the need to deliver the right product to the right patient became more and more the focus of regulatory bodies worldwide, GS1 was well-poised to support these efforts. We created partnerships to assist as activities and regulations continued to evolve. GS1 Healthcare’s outreach and partnerships “paved the way” for world-wide implementations, which contribute improving patient safety.

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Scott Mooney | Vice President Operations | McKesson Pharmaceutical Solutions and Services | GS1 Healthcare Tri-Chair

The next years were important for the GS1 Healthcare community, bridging the gap between vision and action. Improving care processes and efficiency requires continuity of care overcoming numerous barriers. Being able to rely on globally harmonised identification standards is critical. This is where GS1 is able to play a role for the benefit of the patients.

GS1 Healthcare also expanded its global outreach, with GS1 Member Organisations collaborating locally and globally and adoption beginning in locations such as Argentina, Australia, Denmark, Japan, Portugal, Turkey, the UK and US. In addition, work to help improve the vaccines supply chain moved forward with the WHO, GAVI, UNICEF and local implementation partners around the world. Unique Device

Identification (UDI) emerged as a major focus point, with the developing regulations of the US FDA and other regulatory bodies.

Concentrating on the implementation of standards in hospitals, GS1 Healthcare created Project Imagine to more effectively engage healthcare providers and raise awareness of GS1 standards and their benefits. In 2013, GS1 Healthcare established the GS1 Healthcare Provider Advisory Council (which was later replaced by the current Clinical Advisory Council) composed of hospital and pharmacy experts and introduced two awards: the Provider Recognition Award for individuals and the Provider Implementation Best Case Study Award for hospitals.

Applying our global strategy

2016-2020



“The last five years have shown incredible growth for GS1 Healthcare. With completion of the GS1 Healthcare strategy, we have begun executing that strategy and at the same time supported our global GS1 Healthcare Members and GS1 Member Organisations (MOs) worldwide. It is with vital importance that we continue to harmonise global approaches, ensuring our key vision remains feasible with our primary focus in delivering patient safety and benefit around the world.

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Mark Hoyle | Technical Director, UDI | Commercial Regulatory Affairs | GS1 Healthcare Tri-Chair

Over the past five years, GS1 Healthcare has gone on to expand our activities. Progress continued, as GS1 standards were implemented across clinical and business processes and deeper into healthcare provider environments. New developments in standards and digital tools helped to accelerate these implementations - all the way to the patient.

Outreach included conferences with record-breaking participation, including in China, Colombia, Ethiopia, Germany, India, the Netherlands, Nigeria, Thailand, UAE and the US. These truly memorable events shared powerful knowledge and compelling experiences about using GS1 standards to enable traceability and access to safe medicines for patients around the world. Each event brought hundreds of international

stakeholders together to share experiences, learnings and benefits of implementation..

In 2019, access to the healthcare provider database was extended to all healthcare stakeholders. The database continues to grow with more than 125 case studies about hospital implementations of GS1 standards worldwide. For many years, the GS1 Healthcare Public Policy database has been a very valuable instrument. Together with the Interactive World Map launched in 2019, these tools provide complete and real-time information about all existing and developing regulatory requirements related to the use of GS1 standards. These are open to all GS1 Healthcare global members and MOs. GS1 Healthcare continues to enhance communication with our members by delivering valuable member stories about successful implementations of GS1 standards in the GS1 Healthcare Reference Books.

Together, we are looking to the future



“We would like to take this opportunity to thank all of our GS1 Healthcare community for helping us succeed and to invite you to celebrate this accomplishment with us. Together, we are truly making a difference. I know we will continue to come together as a community that is committed to making healthcare safer and more efficient for patients everywhere.

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Miguel Lopera | CEO | GS1 Global Office

Since 2016 GS1 Healthcare continued to make working with regulatory bodies a priority, supporting pharmaceutical traceability and Unique Device Identification (UDI) regulations, standards and policies in more than 70 countries globally.

In 2020, efforts are being increased to ensure all healthcare stakeholders— providers, distributors/ wholesalers, manufacturers, regulators, solution & logistics providers and GS1 Member Organisations - have access to the necessary knowledge and assistance to implement GS1 standards. As a new decade begins, our community is determined more

than ever to drive successful harmonisation and implementation of global standards.

GS1 Healthcare was honoured to assume the chair position of the Joint Initiative Council in 2020, a group of international Standard Organisations, working together towards interoperability.

GS1 remains committed to facilitating the work of GS1 Healthcare to improve processes that will benefit patient's lives. We can all be very proud of what we have achieved so far and look forward, with confidence, to what is yet to come.

To mark this special birthday, GS1 Healthcare will donate 6600 bars of soap for hand washing to help prevent the spread of disease at health centres, schools and child-friendly places, through the UNICEF donation programme



SAFER, MORE EFFICIENT CARE STARTS WITH A SIMPLE SCAN.

Starting Strong

2005

- Global GS1 Healthcare User Group (HUG) is formed
- The National E-Health Transition Authority (NEHTA) in Australia chose to use GS1 standards



2006 & 2007

- GS1 signs memorandums of understanding with two other Standards Developing Organisations (SDOs), HL7 and ICCBBA.
- Eucomed position paper recommending implementation of GS1 published



2008 & 2009

- The Institute for Safe Medication Practices Canada (ISMP) and Canadian Patient Safety Institute (CPSI) endorse the adoption of GS1 standards
- First GS1 Healthcare Reference Book published
- Three global GS1 Healthcare conferences held per annum



2011

- The EU Falsified Medicines Directive Released
- Argentinian National Drug Traceability programme using GS1 standards goes live



2012

- 99% of medical devices supply in Japan identified with a GTIN
- McKinsey report "Strength in Unity" published



2013

- GS1 first accredited UDI issuing agency for the US FDA UDI rule



2010

- Turkish Track & Track system for pharmaceuticals using GS1 standards commences
- US Healthcare organisations confirm support for GLN 2010 Sunrise and GTIN 2012 Sunrise



2014

- Healthcare GTINs in GDSN exceed 1 million (33% growth in 1 year)
- The Danish Minister states "all Danish hospitals in the future have to use GS1 standards"
- The UK Department of Health eProcurement strategy mandates GS1 standards



2016

- Increased focus on working with healthcare providers through Project Imagine
- Implementation kit for EDI standards in healthcare published



2017

- Recommendation for GS1 standards by USAID and UNFPA
- New GS1 standard for Basic UDI-UDI based on the Medical Devices Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR) published
- Asia Pacific Economic Cooperation (APEC) Roadmap on supply chain integrity and drug safety released



2018

- First global GS1 Healthcare African Conference in Addis Ababa, Ethiopia
- New 2018-22 Healthcare strategy released
- Regulatory Roadmap: Traceability of Medicinal Products is published

2019

- Traceability call to action signed in Lagos by 25 African regulatory bodies
- GS1 designated as UDI issuing entity for the EU MDR/IVDR
- First Clinical Trials standard for investigational products

2020

- GS1 Healthcare participates at World Economic Forum in Davos
- Chair of Joint Initiative Council
- Over 3 million Healthcare GTINs in GDSN (May 2020)



2015

- WHO preferred vaccine characteristics include the presence of a barcode that "should conform to GS1 standards"
- GS1 holds the 27th GS1 Healthcare conference in Mexico City



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we are
looking to
the future*



2005-2020