

News story: MHRA GxP Data Integrity Definitions and Guidance for Industry

Updated: Updated to link to the final guidance on GxP data integrity

[View the final Guidance on GxP data integrity.](#)

This
[consultation document](#)
(PDF, 599KB, 14 pages)

provides guidance on the data integrity expectations that should be considered by organisations involved in any aspect of the pharmaceutical lifecycle or GLP studies regulated by MHRA.

The guidance is intended to be a useful resource on the core elements of a compliant data governance system across all GxP sectors (good laboratory practice, good clinical practice, good manufacturing practice, good distribution practice and good pharmacovigilance practice).

It addresses fundamental failures identified by MHRA and international regulatory partners during GLP, GCP, GMP and GDP inspections; many of which have resulted in regulatory action.

The document should be read in conjunction with the applicable regulations and the general guidance specific to each GxP.

We welcome your comments via the
[comment sheet](#)
(MS Word Document, 224KB)

which can be emailed to inspectorate@mhra.gov.uk

Deadline for comments: 31 October 2016

Press release: Derbyshire man reeled in for fishing without a licence

The Environment Agency is reminding anglers of the importance of having a rod licence, after a 48 year old Derbyshire man was ordered to pay over £500 in fines after being found guilty of fishing without a licence.

Nathan Hughes of Duffield Road, Little Eaton, was charged £523 after being found in breach of the Salmon and Freshwater Fisheries Act (1975) in January 2018.

The case heard at Northampton Magistrates Court was brought by the Environment Agency following the discovery of the offender on the River Soar at Kegworth.

Following the verdict, an Environment Agency spokesman said:

We are pleased with the outcome and hope that it will provide as a deterrent for any angler thinking of fishing without a licence. All the money raised from rod licence sales is used to protect and improve fish stocks and fisheries, benefitting anglers and those cheating the system will feel the full extent of our legal powers.

Every year across the country, thousands of anglers are prosecuted for not having a fishing licence. As well as swindling other anglers, fishing illegally can carry a hefty penalty. Getting caught without a licence could land a fine of up to £2,500.

Any angler aged 12 or over, fishing on a river, canal or still water needs a licence. An annual licence costs from just £30 (concessions available) and is available from www.gov.uk/get-a-fishing-licence or by calling the Environment Agency on 0344 800 5386 between 8am and 6pm, Monday to Friday.

Anyone with information about illegal fishing activities can contact the Environment Agency Incident Hotline on 0800 80 70 60 or anonymously to Crimestoppers on 0800 555 111.

Press release: Further boost for UK auto sector as PSA confirms new generation of vans to be built in UK

- Business Secretary welcomes announcement during visit to Vauxhall's Luton plant, where next generation Vivaro to be produced from 2019
- move ensures plant's long-term future, with a commitment from the company to invest further in the plant and safeguard 1,400 jobs
- agreement secured in part thanks to £9 million of government funding alongside local support and underlines success of UK's landmark Industrial Strategy Automotive Sector Deal

The UK's world-leading auto sector received a further vote of confidence today (Wednesday 4 April) as PSA announced it will produce the next

generation Vauxhall Vivaro at its Luton site from 2019. The announcement is testament to the plant's highly-skilled workforce and will ensure manufacturing remains in the UK for years to come.

Business Secretary Greg Clark welcomed the decision during a visit to the plant in Bedfordshire today alongside PSA group Chief Executive Carlos Tavares, leader of Luton Borough Council Hazel Simmons and Union leaders.

As part of the announcement, Vauxhall has committed to invest further in the plant, supplementing £9 million of government funding to install a new manufacturing platform. The deal has been aided by a range of support from local government, including help with recruitment, skills and efficient energy.

Prime Minister Theresa May said:

Vauxhall's decision to invest in the United Kingdom is testament to the world-renowned expertise of the British automotive industry and workforce.

Through our modern Industrial Strategy, we are investing in the technological developments of tomorrow – ensuring we remain the natural choice for innovative firms to prosper.

The platform will allow the Luton plant to produce the next generation of Vivaro vans, with the aim of increasing existing output from around 70,000 vehicles per year to 100,000. The platform will also optimise manufacturing processes allowing the plant to bid for future vehicle lines as they become available.

Business Secretary Greg Clark said:

Today's decision is a vote of confidence in Vauxhall's high skilled workforce and the UK's world leading automotive sector. This investment in upgrading the production platform will safeguard and grow jobs, ensuring the future of the Luton plant well into the next decade and help ensure the plant is well positioned for future Vauxhall models to be made in the UK.

We have been clear in our commitment to the automotive sector which is why, through the Industrial Strategy, we established a landmark Automotive Sector Deal that will see us working with industry to put the UK at the forefront of new technologies.

Through our ambitious Industrial Strategy the government is building on our existing strengths. Our landmark [Sector Deal](#) in January between government and the automotive industry was a vital moment in establishing the UK's leadership in meeting the Future of Mobility and Clean Growth Grand Challenges. Today's announcement will help secure the jobs of more than 1,400

people in Luton and builds on the firm's strong association with the town for more than a century.

SMMT CEO Mike Hawes said:

This announcement is great news for the UK automotive sector and, especially, the Luton plant. The UK continues to be a centre of excellence for vehicle production thanks to our engineering expertise, high levels of productivity and a collaborative relationship with government which has enabled us to build a robust industrial strategy and a sector deal.

We will continue to work with policy makers to ensure the UK remains as competitive as possible now and in the future so we can continue to build on our long heritage in vehicle manufacturing.

The UK's automotive sector continues to thrive with the UK currently the fourth largest European car producer with the highest productivity among Europe's automotive producing nations. The sector generates £14.6 billion, representing 8.2% of the UK's total manufacturing gross value added. The sector deal lays the framework for further UK investment in our world-class automotive industry such as Toyota's announcement in February that they will build the next generation Auris at their Burnaston plant in Derby.

The UK's Industrial Strategy is a long term plan to build a Britain fit for the future through a stronger, fairer economy. Through this we will help businesses to create better, higher-paying jobs – setting a path for Britain to lead in the high-tech, highly-skilled industries of the future.

Construction company worker suffers life threatening injuries

A construction company was sentenced today for safety breaches after a worker suffered life threatening injuries.

Sheffield Magistrates' Court heard that, in September 2016, a 48-year-old employee of K. D. S. Construction Company Ltd was working in a 2-metre-deep excavation when he was struck on the head and pinned down by a large segment of concrete. He suffered multiple injuries, including fractures to his skull, ribs, left arm and vertebrae.

An investigation by the Health and Safety Executive (HSE) found that the construction company had been contracted by Abbey Forged Products Limited to carry out groundworks for the installation of a new underground water

drainage system at the company's Beeley Wood Works site in Sheffield.

The investigation also found that KDS employees had dug out a number of excavations for the new tanks and pipework. After one tank had been installed, work started on another excavation for a second tank adjacent to the first. While this was being dug, one of the groundworkers was asked to cover over some pipework which was sticking out of the first tank to protect it from being damaged by backfill. When he descended into the excavation to do this, a section of unsupported concrete which was overhanging the excavation broke off and fell onto him.

K.D.S. Construction Company Ltd of Taylors Court, Rotherham pleaded guilty to breaching Section 2(1) of the Health and Safety at Work etc. Act 1974 and was fined £70,000 and ordered to pay costs of £4,016.15.

After the hearing, HSE inspector Alison Outhwaite commented: "The employee's injuries were life changing and he could have easily been killed. This serious incident and devastation could have been avoided if basic safe guards had been put in place.

"This case highlights the need to be aware of the risks of working in and near excavations. The groundwork industry need to appreciate the risks even where excavations are thought to be 'shallow' or the ground considered to be stable. As HSE guidance states. 'Any unsupported excavation will be safe ONLY if its sides are battered back sufficiently or if the excavation is in sound rock (HSG150).

"If a suitable safe system of work had been in place prior to the incident, the life changing injuries sustained by the employee could have been prevented."

Notes to editors

1. The Health and Safety Executive (HSE) is Britain's national regulator for workplace health and safety. We prevent work-related death, injury and ill health through regulatory actions that range from influencing behaviours across whole industry sectors through to targeted interventions on individual businesses. These activities are supported by globally recognised scientific expertise. www.hse.gov.uk
2. More about the legislation referred to in this case can be found at: www.legislation.gov.uk/
3. HSE news releases are available at <http://press.hse.gov.uk>

News story: Dr Patrick Vallance takes

up his appointment as Government Chief Scientific Adviser

The role of the GCSA is to advise the Prime Minister and government on all matters related to science and technology and to ensure that policies and decisions are informed by the best scientific evidence and strategic long term thinking.

The GCSA is head of the Government Science and Engineering (GSE) profession and Co-chair of the independent Council for Science and Technology which provides high level advice to the Prime Minister.

Patrick Vallance said:

Harnessing the very best science and technology has never been more important to the UK's economy, future and citizens. Science and technology have a vital role to play at the heart of policy making and I look forward to working with colleagues to ensure the government has the best possible advice, from the best experts, based on the strongest evidence.

It is essential that we have world class scientists and engineers working in government. Excellence can only be delivered by a diverse and inclusive profession. It will be a key priority for me to ensure we go further to improve representation across the profession.

Before joining the Government Office for Science, Patrick Vallance was President, R&D at GlaxoSmithKline (GSK) from 2012. Prior to this, he was Senior Vice President, Medicines Discovery and Development and he joined the company in May 2006 as Head of Drug Discovery.

You can find a full biography for Dr Patrick Vallance at:
www.gov.uk/government/people/patrick-vallance