



**COMPLIANCE**  
INSIGHT, INC

## ***GxP Infusion***

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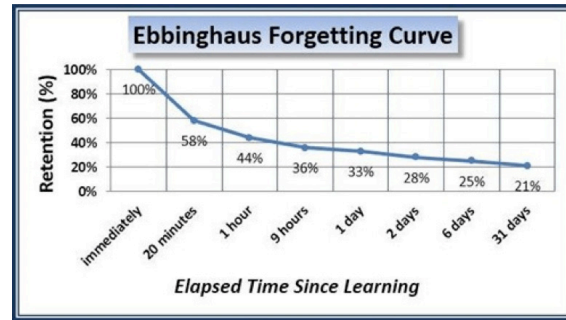
# GxP INFUSION

## “GET ENTHUSED, GET INFUSED!”



### THE BACKGROUND STORY

The beginning...looking over the data from FDA inspections for the past ten years, an assessment was performed to ascertain why people would go through training but still have issues. The programs and techniques were in place but the outcomes were still the same. It was decided to further assess the human mind and learning capability. The astonishing statistics:



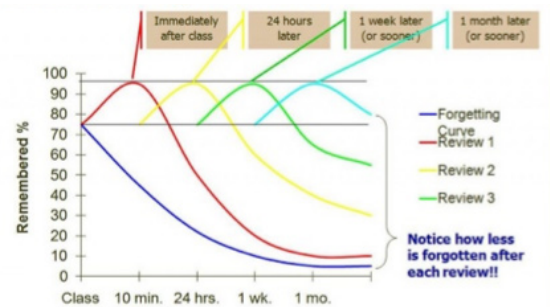
- After one hour, 50% forgotten.
- After just two days, almost 75% is forgotten
- Within a month, 80% is gone.

### QUESTIONS TO CONSIDER:

Who provided GxP training at your firm last year and what was the topic?

Had anything improved or changed because of the training?

It was a critical discovery of a flaw that we, as an industry, perpetuate: Annual GxP Training with the expectation of changing habits, was not much more than a compliance event.



If you learn something, and **it is important to you, and you can connect it with many things you already know**, your memory retention will be very high

### OVERCOMING THE CURVE

Our approach is simply different: Reinforce a message with spaced repetition to achieve real learning – real results! The more relevant, meaningful connections you can make with the new information in your mind, with things you already know, the better your memory retention over time.

### THUS, THE GXP INFUSION PROGRAM WAS BORN...

Are you serious about infusing GxPs into your company's DNA, or is GxP training just a compliance event? GxP Infusion is a 6-month workforce development program with a specific GxP topic that you can tailor for your specific context and culture. This course meets the Code of Federal Regulations GMP requirement of “ongoing GMP training on a regular basis.”

Through a password protected portal on our website, you will access expertly designed workforce development materials each month supporting the 6-month theme. The package is a Trainer Program – designed for the on-site training person to tailor as necessary and then to deliver the message to the workforce.

#### Each Package Includes:

- 6-Month running themes based on the Three Sins of GMP.
- Spaced repetition of the message delivered throughout the month.
- Approximate half hour training video, broken down into three-10 minute segments.
- Visual PPT presentations explaining the what, why and how.
- Reinforcement PPT slides to be delivered to participants on a specific schedule.
- Leader's Guide specific to the theme.
- Participant worksheet.
- Support Posters to be printed out and strategically placed throughout the facility (lunchroom, bulletin board, etc.).
- 10 Question Quiz at the end of the 6 months to assess success.

#### The Support:

- Access to all training materials through a password protected portal on our website.
- Regular e-mail reminders to keep you on track for the 6 months.
- Help line available for subject matter support.
- Renewal reminders at the end to register for the next 6-month Theme.

### EFFECTIVE AND MEANINGFUL DELIVERY

As a suggestion, you may choose to enhance the provided material with familiar items such as:

- Pictures of your facility, equipment, personnel, etc.
- Your specific goals or messaging pertinent to the topic.
- Company mission and/or vision.
- Specific issues at your facility.

The program is designed for maximum retention of the six-month theme, delivered in planned spaced doses over the course of each month. Enhance and grow your program based on the feedback received. Remember, it is the goal to change behavior and infuse GMPs into the recipient's DNA.

### MEETING THE FDA REQUIREMENTS

To meet the GMP requirements, your firm is required to provide GMP training to all employees. At some point, you will be asked by the FDA inspector to provide an overview of your program, examples of the lessons and documented evidence of execution.

It is highly recommended that an SOP be written specific to this program. In the event you need guidance on a simple procedure, one is included in this program for your use. Provide this program to the inspector showing that you have a planned and periodic methodology to deliver and reinforce a GMP message.

### EMERGENCY GUIDANCE

The GMP Help Line: (513) 860-3512  
FDATrainingTeam@Compliance-Insight.com



# OUR CODE OF COMMITMENT TO YOU

All of the members of Compliance Insight appreciate your commitment to use our services to meet your compliance goals. We, therefore, commit the following actions to you – our partner:

## ETHICAL EXECUTION OF WORK

- Trustworthy – We will:
  - Not deceive, cheat or “milk” a client for time or services performed
  - Be honest and reliable
  - Be loyal, reliable and maintain integrity
- Respectful – We will:
  - Abide by the Golden Rule — do unto others as you would have them do unto you
  - Be respectful of the clients’ money – be a good steward

## EXPERTISE AND SKILLS

- Colleagues assigned to the project will have the skillsets to perform the task
- Being accountable. Ethical people show responsibility by being accountable and pursuing excellence by being diligent and persevering
- Have the ability to respond to expectations
- Own the task assigned

## CUSTOMIZATION OF EXECUTION

- Fitting project actions into the client’s unique circumstances and operations
- Learn the specific processes at the site to understand how best to effectively and efficiently implement compliance

## TIMELINESS

- Rapid response to effectively execute the tasks assigned
- Have skilled colleagues on site and/or actively working to resolve issues quickly

## ACCESSIBILITY

- Easy availability to discuss the project execution with key decision makers

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### Our mission:

Actively engage and align with our clients to move beyond the regulations to compliance that makes sense

### Our vision:

Your first and best choice for decisive insight into GxP compliance!

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## 2016 Pharma Tech Outlook: Top 10 Pharmaceutical Compliance Solution Provider

*“Compliance Insight selected for our Top 10 Pharmaceutical Compliance Solution Providers list has demonstrated a commitment to excellence and gained strong industry credibility,” said Stacey Smith, Managing Editor, Pharma Tech Outlook. “I congratulate Compliance Insight and look forward to its continued success.”*



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